The contribution of nurses, midwives and health visitors to protocol-based care and its variants, and the impact of their contribution on patient and staff outcomes, quality and costs of care

Report for the National Institute for Health Research Service Delivery and Organisation programme
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1   Introduction, context & methodological summary

The NHS Service and Delivery Organisation R&D (NCCSDO) commissioned a Collaboration from the University of Sheffield, Institute of Work Psychology (IWP) and School of Health and Related Research (ScHARR) to study the impacts of Protocol-Based Care (PBC) and its variants in the NHS. Specifically the research aimed to:

1. Identify the settings into which different models of protocol-based care have been introduced;

2. Examine the ways that nurses, midwives and health visitors contribute to protocol based care;

3. Identify the impact of their contribution on organizational, patient and staff outcomes, costs and quality of care; and

4. Assess the overall impact of the introduction of protocol-based care upon their work and their sense of professional identity and capacity.

This report presents findings from a mixed methods research programme designed to address these research aims.

Chapter one provides the context for the research and describes the research methodology. An immediate challenge for the research team was the changing terminology used in this area, both in policy documentation and in local understanding and adoption of PBC. For this reason, terminology and policy context are dealt with here, prior to a description of the specific research aims and methodological approaches used.

In chapter one:

Section 1.1 introduces the concept of PBC and its variants. It describes immediate challenge to the research identified in the local use of terminology and defines 'standardised care' – the term used throughout this report to refer to PBC and variants.

Section 1.2 describes the policy context for the research and three mechanisms by which policy has been translated into practice.

Section 1.3 highlights some of the current debates about the use of standardised care as an initiative for modernising and improving quality in the NHS.

Section 1.4 introduces some of the concepts around rules and bureaucracies that have been drawn on in parts of the research programme.

Section 1.5 presents the specific research objectives and summarises the methods used to examine the impact of standardised care on nurses, midwives and health visitors.

Section 1.6 details the thematic structure of the report and subsequent chapter contents.

1.1 Protocol-based care and its variants

Although 'protocol-based care' featured in The NHS Plan (DH 2000) it was not defined. Subsequently, research has suggested that in practice, protocol-based care is an umbrella term that encompasses a range of clinical care processes, including protocols, procedures, algorithms, care pathways, clinical guidelines, procedures and patient group directives (Rycroft-Malone *et al*. 2004). These clinical care processes are regarded as variants of protocol-based care. Some variants, such as procedures, are well-established in nursing and midwifery, whereas others, such as clinical guidelines, gained prominence as part of the evidence-based medicine movement (Timmermans & Berg 2003). The popularity of each variant seems to fluctuate. For example, in the 1990s integrated care pathways were associated with continuous quality improvement (Beyea 1996) and now, in 2008, the care bundle approach designed to increase the reliability of performing therapeutic interviews is being used by the National Patient Safety Agency to promote patient safety in intrapartum care and neonatal practice (NPSA 2008).

This study found that researching protocol-based care (PBC) was challenging because in practice the term was both defined and used inconsistently. In some cases the 'umbrella' definition was upheld, however, in many others PBC was used as a synonym for a particular care approach (eg care pathways) or to refer to a specific interpretation of protocols as mandatory, prescriptive care. Dependent on the local definition of protocol, the implications for working practice, a key area of this research, could vary considerably. No assumptions could therefore be made about the meaning of the term PBC in any of the research material as this would risk confounding attitudes to a specific approach (the local definition) with the broad range of approaches (Protocol-based care and it's variants) relevant to this study.

1.1.1 Using 'standardised care' in the research

Early findings from the expert interviews confirmed the following points:

- PBC was used inter-changeably with other terms by many interviewees.
- Use of the term PBC risked excluding participants - some potential expert interviewees declined to participate in interviews as they were unfamiliar with the term, despite being recognized experts in variants of PBC.
- The interviews confirmed that there was no consensus around definitions of or characteristics of protocol based care.

The early stages of the systematic literature review confirmed the lack of an established identity for PBC:
- PBC as a search term on its own identified no relevant studies.
- The only way to identify relevant studies for the review was to use the term 'protocol' in conjunction with either 'guidelines' or 'pathways' (ref).
- Very little research was identified on protocol based care. Far more was identified on its variants.

Within the case study work the preferred local term for 'PBC and its variants' was used. Again, considerable variation in meaning was found:

- At three case study sites care pathway was used
- At one site, care guidelines, and
- At the final site protocol was used.

Three of the four fieldwork strands provide a consistent picture of the various ways in which PBC is used and understood in practice. In both interviews and case studies, the fact that the data is collected qualitatively via face to face methods allows for sense making and clarification with the participant/interviewee. In a survey, this is not the case and the survey element of this research faced significant challenges around appropriate terminology. Piloting of the survey with nurses, midwives and health visitors highlighted the conceptual inconsistencies around PBC. Providing a definition of PBC and asking respondents to use this definition was a questionable approach. First because use of PBC could have the effect of excluding some respondents (as it did in the interviews). Second, there was no evidence that PBC had a definitive meaning. Third, because where a definition was given participants at the piloting stage reported difficulty in responding accurately to questions about 'PBC as defined', particularly when it clashed with their own understanding or had a generic definition (eg as an umbrella term).

It was obvious from the early stage of the research that whilst PBC may not be well understood, it's variants (such as protocols, care pathways, clinical guidelines etc) were understood, and were widely used. It was also possible to identify the common purposes of variants of protocol-based care:

- To standardise clinical processes;
- To reduce unacceptable variations in care;
- To support evidence-based practice; and latterly
- To facilitate service commissioning.

Further piloting of the survey established that 'standardised care' was an acceptable 'catch-all' term, understood to refer generically to protocols, care pathways, guidelines etc without the disadvantage of the negative connotations of 'protocols' for many respondents. For these reasons, 'standardised care' was felt to be the best term to use in the survey, making it accessible to all and enabling data on the experience of specific variants of standardized care to be captured more reliably.

Having established with the survey work that standardised care was an acceptable (and connotation free) generic term to cover PBC and its variants, the research team felt that it made sense to continue using the term when it came to writing the research report. Where data or documents refer to a specific form of standardised care, this is emphasised in the text.

1.2 Standardised care: Transition from policy into practice

Two of the primary aims for this research are to understand the settings into which standardised care has been introduced and the extent to which nurses, midwives and health visitors have been involved in its development. Understanding the policy drivers and the mechanisms for translating policy into practice therefore helps to identify the policy intentions for standardised care settings. Looking at the mechanisms for developing and implementing standardised care provides insight into the opportunities for nurses, midwives and health visitors to become involved in the development and implementation of standardised care and whether these approaches have been fully adopted. Both these aspects of standardised care can have significant implications for the impact on staff and other intended outcomes.

1.2.1 The quality framework for the NHS

Standardised care is integral to the policy to modernise the National Health Service in England by reducing unacceptable variations and improving quality. Commissioning and clinical governance are two key mechanisms for putting this policy into place, with commissioning acting as a strategic lever for change and clinical governance supporting quality improvement at an operational level.

The quality agenda was articulated in 'A First Class Service. Quality in the new NHS' (DH 1998). This paper introduced system reform across the whole of the NHS through a quality framework which established a national infrastructure, supported by local action. National standards were to be set by bodies such as the National Institute for Clinical Excellence (NICE, now known as the National Institute for Health and Clinical Excellence). The standards would be delivered locally through clinical governance arrangements whereby each Trust became responsible for continuous quality improvement. There would also be a national surveillance system with performance monitoring by the Commission for Health Improvement (now the Healthcare Commission) which was accountable to Parliament and to the public through annual reports.

Unacceptable variations are wasteful, unfair and costly. The 'A First Class Service' report highlighted a number of factors which lead to variations:

1. The internal market which prevented sharing best practice;

2. The lack of clear national standards which every part of the NHS was expected to achieve;

3. No coherent assessment of the clinical or cost effectiveness of treatments; and
4. *'That the NHS as a public service has not been sufficiently open and accountable about the quality of services it offers to the public'.*

(DH 1998, p6).

1.2.2 The modernisation agenda

The term, protocol-based care featured in The NHS Plan (DH 2000), which marked a commitment to extra funding for the NHS in return for reform, particularly of changes to

working practices and embedding the quality framework described in 1.2.2 into the NHS in England. The Plan stated that by 2004 the majority of NHS staff would be …

> 'Working under agreed protocols identifying how common conditions should be handled and which staff can best handle them'

and that the NHS Modernisation Agency …

> 'Will lead a major drive to ensure that protocol-based care takes hold throughout the NHS' (p83).

At a more practice oriented level, standardised care is referenced in National Service Frameworks (NSFs) that have set quality standards for services provided to specific patient groups and guidance issued by NICE.

In 2005, when the Healthcare Commission commented on reducing variation, they referred to 'standards' and 'guidelines' as ways to reduce the gap between what people who receive the best care and treatment get and those who are missing out. Whilst the language in policy documents had changed from 'protocols' to other specific forms of standardised care, the intent remains the same.

1.2.3 Mechanisms for translating policy into practice

The mechanisms for translating this policy into practice operate at different levels. In this section, three mechanisms are summarised. There are two general mechanisms – commissioning and clinical governance – plus specific guidance about development and implementation of protocol-based/standardised care.

Commissioning is a strategic device for incorporating quality standards into contracts with service providers whereas clinical governance is a quality improvement measure applicable to front-line staff. These are multifaceted and inter-related approaches described separately here to underline the relevance of standardised care for managers and practitioners. The third mechanism is the specific guidance issued by national bodies to support the local development and implementation of standardised care, identifying resource available to nurses, midwives and health visitors engaged in the development of standardised care.

1.2.4 Commissioning services

Practice-based commissioning was introduced in 2005 with the aim of increasing patient choice by allowing GPs to identify a variety of NHS and independent sector providers and, in the longer-term, to directly provide or commission new services themselves (DH 2004). World class commissioning (DH 2007a) now sets the strategic direction for outcome-based, integrated commissioning across the local health economy by Primary Care Trusts (PCTs) and Local Authorities.

Two of the competencies for world class commissioning indicate the need for quality standards to give local accountability. A competency about procurement and contracting, states that 'PCTs can specify quality standards and outcomes to facilitate good working relationships with their providers, offering protection for service users and ensuring value for money' (DH 2007b p42). The second competency about collaborating with clinicians,

states that the PCT will work with *'clinical colleagues … along care pathways both to spread best practice and rigorous standards to hold clinicians to account'* (DH 2007b p21).

1.2.5 Clinical governance

The quality framework (DH 1998) is implemented at a local level through clinical governance. There are seven elements of clinical governance reflecting the characteristics of the reform agenda for the public sector. The elements are:

1. Patient, service user, carer and public involvement;

2. Risk management;

3. Clinical audit;

4. Clinical effectiveness;

5. Staffing and staff management;

6. Education, training and continuing personal and professional development; and

7. Use of information to support clinical governance and health-care delivery.

The Commission for Health Improvement reviewed the clinical governance systems of all Trusts and rated their performance. The successor organisation, the Healthcare Commission, now uses core and developmental standards to report on Trust quality. Two of these standards relate to safety and clinical and cost effectiveness. For example, trusts are asked to provide evidence that they have conformed to nationally agreed best practice as defined by NICE guidance.

Standardised care operationalises several elements of clinical governance, particularly risk management, audit and clinical effectiveness. A recent report, 'Safe Births: Everybody's Business' (King's Fund 2007), demonstrates the inter-play between standards, audit and effectiveness. The report states that …

> *'Safe practice must be based on evidence about interventions that work, as set out in guidelines, protocols and other forms of guidance'* (p5).

In response to the problems of guidelines not being available or useful, the report recommends a single set of evidence-based guidelines, supplemented by one-page protocols and staff training with regular audit to ensure implementation. Standardised care is a method for promoting safety by incorporating the best available evidence into documents that guide the decision-making and action of front-line staff. The standards are then audited, to monitor performance and achievement of the agreed quality standards.

1.2.6 Specific guidance on the development process

In 2002 and 2005, the Modernisation Agency (MA), as the body charged with embedding protocol-based care into the NHS (DH 2000), produced a series of documents about developing and using protocol-based care. There was a step-by-step guide to developing protocols (MA/NICE 2002a,b,) and in 2005, six case studies were published that demonstrated how

protocol-based care was being used in a variety of settings. The NHS Institute for Innovation and Improvement website now contains the guidance about protocol-based care, which is identified as a service improvement tool, but does not differentiate protocols specifically within service development.

The National Institute for Health and Clinical Excellence (NICE) is a major source of guidance about the implementation of standardised care. Its remit was extended to cover implementation in 2004. The aim was to encourage and promote the uptake of NICE guidance. This is done in a number of ways including 'intelligent' dissemination, providing practical support, which included generic and guidance specific tools, sharing learning and by developing educational material.

Standardised care then can be seen as a component of the drive to modernise the NHS in England and to achieve a variety of related aims/functions.

1.2.7 Protocol-based care: nursing, midwifery & health visiting

The NHS Plan (2000) refers to 'Protocol-based care' in the chapter for nurses, midwives, therapists and other NHS staff. This chapter also contained the Chief Nursing Officer's ten key roles for nurses and midwives that were prefaced by a paragraph that foresaw radical change in the roles and responsibilities of these staff who provide the majority of the workforce …

> *'The new approach will shatter the old demarcations which have held back staff and slowed down care. NHS employers will be required to empower appropriately qualified nurses, midwives and therapists to undertake a wider range of clinical tasks'* (DH 2000 p83).'

A key intent of standardised care is as a mechanism for safely extending the scope of nursing practice and establishing new services, such as NHS Direct and walk-in centres, where nurses provide the first point of contact and care is given in accordance with evidence-based, decision-support systems.

1.3 Standardised care: nursing, midwifery & health visiting

Nurses, midwives and health visitors constitute the largest component of the workforce within the NHS, with over 686,800 practitioners registered with the Nursing and Midwifery Council (NMC, 2007). Standardised care has the potential to effect far reaching changes in the way nursing is carried out; on the experience of care for patients and on the experiences of work not only for nurses, midwives and health visitors, but more widely within the NHS.

To some extent good practice guides and written advice have always existed within health care. The main difference between previous approaches such as ward policy and procedure manuals and more recent forms of standardised care is the aim to introduce evidence-based principles into the delivery of care (Gerrish *et al* 2007) ensuring that the best evidence is used, thus reducing variations and improving safety. As such, the aims of standardising care are unquestionably positive; however such approaches are not without criticism. The rules, regulations and guidance that seek to iron out unacceptable variations in type and quality of care may also have a profound effect on nurses', midwives' and health visitors' experience of work. Standardised care has the potential to impact on existing working practices and relationships in a number of ways. There can be

both positive consequences, such as the support they provide for newly qualified staff or expanded nurse roles. Equally, there can be negative impacts, such as the restriction of clinical autonomy or the reduction of opportunities for gaining experience and clinical judgement which could have considerable consequences for professional identity and competence or skill development.

In addition, there is debate about the extent to which standardised care working can impact on job satisfaction or lead to the development of a working 'by rote' approach, both of which can impact negatively on safety or lead to the demise of nursing knowledge and skills (Wilson *et al*, 2006; Carryer *et al*, 2007; Porter *et al,* 2007; Shields & Watson, 2007).

In some cases the uncertainty extends further. There is debate around the extent to which such forms of care are actually applied in practice, their impact on clinical judgement and safety and their suitability as a method of modernisation given the complexity of making change happen.

As well as the aims of standardised care highlighted above, Lawton & Burton (2000) have identified many benefits/rationales often claimed for implementing standardised care, including such outcomes as improved multi-disciplinary team working. They question the extent to which standardised care is really a panacea for organisational issues.

1.3.1 Are standardised care approaches used?

The extent to which standardised forms of care are applied is debated. Some have argued that there is little empirical evidence on the tangible effect or influence of various forms of standardised care on nursing practice (Flynn & Sinclair, 2005). Whittle and Hewison (2007) report that in an RCN survey of all Trusts within the UK, 11 per cent of Trusts accounted for 50 per cent of care pathways reported. Grilli and Lomas (1994) reported a 54.5 per cent compliance rate with clinical guidelines from a review of 23 studies. In a recent survey of just under 600 nurses, Gerrish *et al* (2007) found policy and procedure manuals ranked fourth amongst the sources of knowledge drawn on by nurses, coming after experiential sources such as information from fellow professionals, peers and personal nursing experience.

Within the context of multi-disciplinary teams there is also the question of the consistency with which standardised forms of care are adhered to. McDonald *et al* (2005) found differences in attitudes towards guidelines in multi-disciplinary teams, with nurses seeing guidelines as a key element in providing safe good quality care. In contrast, the doctors in their study viewed guidelines as unnecessary and potentially even harmful. Findings like this highlight the tensions that standardised care can bring to a multi-disciplinary team, in direct contrast to a supposed benefit which is to enhance multi-disciplinary team working (MA/NICE 2002).

1.3.2 Impact on clinical judgement

One of the main concerns expressed in the literature about the impact of standardised forms of care is the extent to which it can reduce the scope for clinical judgement. Discretion is a key variable in organisational research, shown to be linked to a wide range of individual and organisational outcomes. Standardised care has the potential to limit

clinical judgement/discretion with numerous potential consequences. In a small qualitative study Flynn & Sinclair (2005) found that staff deviated from protocols and suggested that the ability to make a clinical judgement based on experience was perceived as more credible. Although the benefits of standardised care were agreed upon by the interviewees in this study, it was felt that they could replace clinical judgement. Flynn & Sinclair report that some nurses felt constrained by standardised care that did not take into account the level of nurse experience. This is a finding replicated elsewhere. Wood (2003), in a systematic review of integrated care pathways, listed strengths and weaknesses, including discouraging clinical judgement and stifling innovation and progress. McDonald *et al* (2005) found several examples of evidence for …

> '*guideline compliance to become an end in itself with some members of staff losing sight of the overall aim of the guidelines, or at least displaying an unquestioning acceptance of their contents.*'

Flynn & Sinclair (2005) conclude that whilst nurses need clear guidelines for their practice, at the same time the guidelines should encourage and nurture the development of clinical judgement.

1.3.3 Impact on safety

A key rationale for the use of standardised forms of care is the improvement in risk management (Lawton & Parker, 1999; McDonald *et al*, 2005). However, qualitative research by McDonald *et al* (2005) highlights the opposing view of doctors and nurses with regard to protocol violation, suggesting a greater focus on rule adherence rather than safety amongst the nursing sample in their study when compared to doctors. They highlight the challenges this presents to creating a 'safety culture' which …

> '*requires a shared set of beliefs, attitudes and norms in relation to what is seen as safe clinical practice.*'

They conclude that the production of guidelines, rather than developing an understanding of the unwritten rules which govern clinical behaviour, can undermine trust in multi-disciplinary teams and may act as a threat to, rather than an enhancer of good safety climate.

1.3.4 Complexity of change

In an organisation as large and complex as the NHS, standardised care needs to be seen in the context of one form of change in a decade of reform and modernisation. The complexity of organisational change in the NHS had been explored in recent SDO reports (Iles & Sutherland, 2001; Fitzgerald *et al* 2006; Greenhalgh *et al* 2004). As Iles and Sutherland point out:

> '*Organisational change is chaotic, often involving shifting goals, discontinuous activities, surprising events, and unexpected combinations of changes and outcomes.*' (p16)

> In the NHS '*change is never likely to be straightforward and linear, not least because of the size and complexity of the organisation. Change also takes place in the context of multi-professional groupings and organisations.*' (p80)

A further aspect of the debate around standardised forms of care is the extent to which such approaches can be applied in practice, given the complexity of implementing change. Whittle and Hewison (2007) note the potential for integrated care pathways to provide many benefits such as promoting multi-disciplinary, patient focused care, assisting in the implementation of evidence based care, improvement in communication and supporting clinical governance, but make the point that such success is contingent on the way the process is carried out. They note that many of the weaknesses of integrated care pathways revolve around the implications of changing patterns of work.

Whittle and Hewison (2007) argue integrated care pathways can be successful where they apply the principle of involving professional groups working together to produce collective solutions. However, evidence from Gerrish *et al* (2007) identifies insufficient nursing time and resources for both the reviewing of evidence and implementing changes to practice. This leads the authors to question the realism of expecting nurses to access, appraise and interpret research findings given the complexity of and time needed to conduct a systematic review. This point is reinforced by evidence from Flynn and Sinclair (2005) who point out the need to ensure that standardised forms of care are accurate in content and entirely up to date if they are to be credible.

1.4 Good rules and bad rules

Wong and Chung (2006) summarise views about explicit rules in nursing by suggesting that they may be perceived as bureaucratic mechanisms that control and limit autonomy, or they may be seen as enabling role expansion into new specialist areas.

Part of the complexity inherent in this debate is the extent to which standardised care is used to meet multiple ends including risk management, quality improvement, evidence based practice, reducing variations in practice and cost control (Lawton & Burton, 2000). It is argued that the extent to which any form of standardised care will have positive or negative impacts depends to some extent on its purpose and the context into which it is introduced. Lawton and Burton argue that the situation is compounded by the lack of direct mapping of terminology with objectives; this supposes that distinct forms of standardised care exist and that they are differentially suited to certain purposes or settings.

It is argued that the extent to which standardised forms of care have positive or negative consequences may well depend upon how they are perceived by users (for example as helpful or restrictive) and the suitability of such approaches for the setting or specific activities in question (including complexity, staff experience or quality of evidence).

One debate in the wider (non health) literature that addresses many of these concerns is about degrees of formalisation in bureaucratic organisations. Adler and Borys (1996) present a conceptual framework that is helpful in understanding how and when good rules and bad rules are formed. They propose that formalisation can have both positive and negative consequences and each will hold under different circumstances.

Adler and Borys argue that formalisation which provides committed employees with access to accumulated organisational learning and best practice can support employees in better mastering tasks and functions and, as a result, such rules are perceived

positively by employees who embrace work procedures that are appropriately designed and implemented. Formalisation which, on the other hand, exists to force compliance, where any deviation from standard procedure is suspect and adherence to the rules helps demonstrate compliance to supervisors rather than helps users determine if a task is going well or how to deal with contingencies, are likely to have negative impacts such as reduced satisfaction, deskilling or reduced performance.

It can be seen how existing debates around standardised care incorporate many of the dimensions covered by the Adler and Borys conceptual framework. Key in determining the impact of standardised care will be how employees perceive the rules they are asked to apply. Formalisation does not need to make work foolproof, but can be designed to enable employees to deal more effectively with contingencies. Research in other sectors has linked 'good' rules to increased commitment, motivation, satisfaction and reduced emotional exhaustion, alienation, role conflict and ambiguity. The Adler and Borys framework therefore offers an important theoretical viewpoint on this research, providing as it does, help in comprehending the conflicting debates about standardised care and in exploring the circumstances in which good rules can flourish.

1.5 Research objectives & methodological summary

In order to address the research aims stated in section 1, the project had four distinct methodological strands with the following specific objectives:

Interviews with opinion leaders

Conduct interviews with opinion leaders to:

- understand current issues and developments in standardised care,
- identify ongoing research, and
- identify other professional activities relevant to the current study.

Systematic literature reviews

Undertake a critical review of the literature to:

- examine existing evidence on protocol-based care development and implementation with specific reference to the roles of nurses, midwives and health visitors.

National Survey

Survey a structured random sample of clinical specialisms to

- identify the extent of use of standardised care, and
- identify the range of settings into which it has been introduced.

Case Studies

Identify a range of case study settings and use Trust, specialism and individual level approaches to investigate both protocol-based care approaches in use and their introduction, using both qualitative and quantitative methods. Via the case studies:

- Investigate the involvement of nurses, midwives and health visitors at the following stages of standardised care development – the initiation of the standardised care, its construction, implementation and evaluation.

- Identify what form this contribution takes, what influences the extent of their contribution, and

- Identify what impact this has on job role, job engagement, autonomy, skill use, job satisfaction, professional identity, capacity and other relevant outcomes.

- Assess the potential cost implications of standardised care using modelling techniques, and

- Illustrate how costs may vary through the contribution of nursing, midwifery and health visiting personnel, and assess how generalisable the results are to other settings.

1.5.1 Changes to the methodology

Over the course of the research and in response to emerging findings, certain aspects of the methodology were changed or extended to provide more detailed information in relation to the research aims and objectives. The main developments are detailed below:

1. Opinion leader interviews were extended to cover current front-line practitioners as well as policy and research expertise.

2. Systematic literature review searches were extended to reflect range of terms used to describe protocol-based care and its variants.

3. Systematic literature reviews were expanded to include a review of the economic impact of standardised care.

4. Systematic literature review analysis was split, one review focusing on development and implementation, the other one on the impact on nurses, midwives and health visitors of working with standardised care.

5. The survey was refocused in light of the prevalence of forms of standardised care, to examine the experiences of a random sample of nurses, midwives and health visitors directly (in the place of a national survey looking at the views of clinical and medical leads on the use of standardised care and smaller, non-random samples of individuals experiences via the case studies).

6. The economic evaluation, in light of the limited evidence available, was re-designed to assess costs in three case study sites and propose a framework for how this might be done more routinely in the future.

7. Two case studies, initially designed as longitudinal studies, had to be shortened. One was due to the delay in the publication of the NICE guidance on intrapartum care from February 2007 to September 2007; and the second delay was for access and operational reasons at the case study site.

A summary table of the aims, objectives and methodologies is presented in table 1.1

1.5.2 Research group and expert advisors

A multi-disciplinary team, lead by Malcolm Patterson, Senior Research Fellow from the Institute of Work Psychology (IWP), University of Sheffield, conducted the research. The team comprised occupational psychologists from IWP, nurse researchers, health economists and an information scientist from the School of Health and Health Related Research (ScHARR) at the University of Sheffield. The study started in June 2004 and ended in March 2008.

The research was supported by a panel of expert advisors, who acted as 'critical friends', offering advice on the development of research tools, and methodological approaches, considering the implications of the emerging findings and giving feedback on the final report. The expert panel met four times during the study. The expert advisors are named in appendix 8.

1.5.3 Summary

This was one of the first major, national studies of protocol-based care. As such it was exploratory, in that it aimed to elicit the experiences and attitudes, and understand the impact and cost of protocol-based care on nurses, midwives and health visitors. A range of primary and secondary research methods were used. Primary, original data was collected from the opinion leader interviews, the national survey and the case studies; whilst the systematic literature reviews involved the analysis of secondary data. The intention was to counter the limitations of each method and to strengthen the findings by triangulating (Robson 1993, Bowling 1997) the evidence from different sources and methods. We drew upon several sources of knowledge (Pawson *et al* 2003) including:

1. the knowledge in policy documents;

2. practitioner knowledge gained from the opinion leader interviews and the lived experience of healthcare staff in the case studies;

3. quantitative and qualitative research and the economic analysis; and

4. theoretical knowledge from occupational/organisational psychology.

Ethical approval for the multi-site study was given by the Eastern Multi Centre Research Ethics Committee, now known as the Cambridgeshire 4 Research Ethics Committee. Research governance approval was also obtained for the opinion leader interviews with NHS staff and for the cases studies based in five NHS Trusts.

Table 1.1 Project aims, objectives and methodologies

Methodologies	Objectives	Aims	Details Found
Semi structured interviews undertaken with 35 opinion leaders	• understand current issues and developments in standardised care, • identify ongoing research, and • identify other professional activities relevant to the current study.	2, 3, 4	Methodology – Appendix 1a Discussion guide – App1b
Systematic review of the literature (practice)	• Identify settings into which standardised care has been introduced • Identify the contribution of nurses, midwives and health visitors to development and implementation • Assess the extent to which development and implementation follows current guidelines • Identify evidence about the impact of standardised care working on nurses midwives and health visitors	1, 2, 3 3, 4	Methodology – App2a Evidence table (development)– App2b Evidence table (implementation)- App 2c References – (development and implementation) App 2d Evidence tables (impact)– App2e References (impact)– App2f
Systematic review of the literature (economics)	• Identify evidence about the costs of standardised care	3	Methodology & Results – App5a References – App5b
Survey of 2,700 nurses, midwives and health visitors	• Provide evidence about the use of standardised care in England by nurses, midwives and health visitors • Examine the impact of standardised care on a range of employee outcomes	1, 2, 3, 4	Methodology – App3a Questionnaire – App3b
Case studies in five Trusts	• Explore the roles and contributions made by nurses, midwives and health visitors to the development and implementation of standardised care • Identify issues, barriers and solutions in real settings • Identify the impact on nurses, midwives and health visitors	2, 3, 4	Methodology – App4a Interview guides – App4b Summaries – App4c to 4g
Economic case studies in three Trusts	• Gather evidence to enable the costing of developing, implementing and monitoring specific examples of standardised care • Develop a framework for future costing of standardised care development	3	Methodology & Summary – App6a Interview Guide – App6b Framework –App7

1.6 Thematic structure of the report

The remainder of this report presents synthesised findings from all research methods in relation to the research objectives. Detailed methodologies and summary findings for each method are presented in separate appendices.

The rationale for the thematic structure is to provide an objective led rather than a method led report and to provide more concise, synthesised evidence in relation to each research question.

Chapter two sets the context for the findings of this research. Early challenges to the research around the meaning and purpose of protocol based care and its variants are explored via survey and interview data and policy documentation. Standardised care is defined and results of a concept analysis (Ilott *et al*, 2006) are presented.

Chapter three addresses the first of the research aims, presenting data on the settings into which standardised care has been introduced and the stated purposes for its introduction.

Chapter four addresses the second of the research aims. It focuses upon what is known about the development and implementation of standardised care in practice: the range of activities involved in development and implementation are outlined and findings from a systematic review of UK studies is presented to illustrate the existing evidence on the contribution of nurses, midwives and health visitors to standardised care in practice. Additional information from the opinion leader interviews is used to provide further depth to the emerging picture. Finally, data on involvement in the development and implementation of standardised care from a national survey of nurses, midwives and health visitors is presented and the factors influencing their involvement are discussed.

Chapter five reports on the qualitative findings in response to research aim four. It explores the impact of standardised care on nurses, midwives and health visitors experience of work. Data from a systematic review of evidence about impact are presented and opinion leader interviews are used to provide a fuller picture of the possible benefits and disadvantages. These issues are discussed in light of wider organisational literature on the formalisation of work.

Chapter six provides further evidence of the impact of standardised care and describes how issues on formalisation were further tested through the national survey of nurses, midwives and health visitors. It identifies the factors associated with 'good' and 'bad' rules and presents survey findings on the extent to which these factors are important in nursing, midwifery and health visiting.

Chapter seven considers the cost of standardised care and the impact on patient outcomes and quality of care. The findings of the economic literature review and three economic case studies are presented. Proxy evidence about patient outcomes and experience are discussed, particularly, patient outcomes resulting from nurse, midwifery and health visitor involvement in standardised care.

Chapter eight summarises discussion of the findings, presents conclusions and implications for policy, practice, education, research and the professions.

2   Standardised care: Definition, status & purpose

Early findings from this research quickly identified that various terms are used to describe standardised forms of care. 'Protocol-based care' first appeared in The NHS Plan (DH 2000) but was not defined, and analysis of data from the literature review and opinion leader interviews revealed that 'protocols', 'clinical guidelines' and 'care pathways' were all used to denote standardised care. Sometimes the terms were used interchangeably as synonyms, by the same informant; and at other times a term would be used consistently, but the status and meaning would vary according to the context, for example, the terms 'protocol' and 'pathway' were applied consistently in two primary care trusts with the same meaning and status being attributed to both terms.

This research highlights that in practice, standardised care was frequently described as fulfilling multiple purposes, with a range of organisational, team, staff and patient reasons given for introducing standardised care into a particular situation. In particular, views on the degree of compliance required by a specific form of standardised care were inconsistent.

The status attributed to standardised care can arguably have a profound effect on the way it is experienced by nurses, midwives and health visitors and the impact it has on quality of care and safety. Understanding the definition, status and purpose of standardised care is therefore an important pre-cursor to understanding how and why nurses, midwives and health visitors are involved in their development and implementation, as well as the likely impacts for patients, staff and quality of care. This chapter describes work undertaken at the beginning of the research to clarify the meaning of standardised care and to identify the distinct features of key variants, namely protocols, clinical guidelines, care pathways and algorithms/flow charts.

In chapter 2:

Section 2.1 examines evidence on the definition and status of the variants of standardised care and concludes by offering a more nuanced understanding of standardised care in specialist and generic settings gained from a concept analysis.

Section 2.2 looks at the multiple purposes attributed to standardised care. Standards and standardisation was the primary purpose, but additional reasons related to the context, such as risk management or role expansion, were often added.

2.1 Standardised care: definition and status

This section draws upon three sources of data to illustrate the meanings attached to the variants of standardised care:

1. Perceptions of the meaning and status of protocols, clinical guidelines, care pathways and algorithms/flow charts obtained as part of the national survey of nurses, midwives and health visitors.

2. Definitions from opinion leaders who were asked to describe the distinctive features of protocols, clinical guidelines and care pathways.

3. Definitions that appear in the public domain, either in the literature or on relevant websites are used to highlight the differences and similarities in language and understanding.

2.1.1 Meanings and status of standardised care

The single most comprehensive source of information about the meaning and status accorded the different terms used to describe standardised care in practice in England comes from the national survey of over 2,700 nurses, midwives and health visitors.

The most common terms for standardised care identified via the opinion leader interviews, literature and policy documents were used to ask survey respondents about meaning (i.e. what the term referred to) and status (the degree to which compliance was required). Respondents were offered four brief definitions to capture the meaning of protocol, clinical guideline, care pathway and algorithm/flowchart. These were i) a specific task or procedure; ii) a set of procedures or activities that are part of the patient journey; iii) procedures for the overall patient journey; and iv) none of these. In investigating the understanding of status related to the degree of compliance, the options were a) mandatory which was defined as requiring compliance; b) advisory which meant they were normally complied with; c) information to support their clinical reasoning and d) none of these. For each variant, respondents were asked to indicate the meaning they attributed to it and the degree of compliance they understood was required by that form of standardised care. Findings from the survey are presented in table 2.1 and show the degree of variation in how these terms are understood.

There is wide variation in the meaning of these four common terms used to denote standardised care. The status and meaning of protocol, clinical guideline, care pathway and algorithm/flow chart are discussed in turn in the next sections, drawing upon data from the survey, the opinion leader interviews and definitions in the public domain.

2.1.2 Protocols

There was most consensus about the meaning and status of protocols. Sixty per cent of survey respondents understood the term protocol to refer to a specific procedure and four out of five respondents viewed protocols as mandatory (i.e. requiring compliance).

Data from the opinion leader interviews, in parallel with the survey findings, associated protocols with prescriptive, mandatory rules that must be followed. Protocols were typically described as …

'a statement of rules … (that) in some way represent official routines.'

Table 2.1. Perceptions of meaning and status for common variants of protocol-based care

	Meaning				Status			
	Specific procedure (%)	Set of procedures (%)	Procedures for patient journey (%)	None of these (%)	Mandatory (%)	Advisory (%)	Informative (%)	None of these (%)
Protocol	59.4	22.5	10.2	7.9	80.5	15.7	3.4	0.4
Clinical guideline	28.9	43.9	15.2	12.1	14.1	62.9	22.9	0.02
Care pathway	3.3	40.2	54.4	2.1	11.2	43.3	40.2	5.3
Algorithm/ Flowchart	21.7	32.4	23.4	22.5	14.9	28.4	44.3	12.4

N=2,711

Protocols were identified as part of the history, practice and regulation of nursing. A nurse manager summarised some of these elements, saying …

> *'Nursing has been used to being more directed by policy, by guide. I mean, the old nursing policy manuals and procedure manuals have been there for years and years and years and it's almost a kind of part of how nursing practice has developed. So actually nursing I think is much more comfortable with protocols than medicine has been historically.'*

The findings from the opinion leader interviews and the survey support definitions found in the literature where protocols are characterised as procedures that require compliance. Layton (1993) defines care protocols as '*agreed interventions for a given diagnosis, symptom or procedure within a time limit'* (p32) and Hewitt-Taylor (2004) states that …

> '*A protocol dictates actions which must be adhered to, whereas guidelines offer less rigid advice. Care protocols, thus have the potential to be less flexible to individual need and to give less scope for professionals to use their professional judgement than clinical guidelines'* (p49).

In North America, practice protocols are associated with legal accountability and responsibility delegated from medical practitioners to nurses (Ebaugh, 1998; Gawlinksi, 1995).

2.1.3 Clinical guidelines

There was less agreement about the meaning of clinical guidelines amongst survey respondents, with 44 per cent defining them as a set of procedures and 29 per cent understanding them to be a specific task or procedure. There was more consensus about

their status, with two thirds considering clinical guidelines to be advisory (as opposed to 14 per cent mandatory and 23 per cent informative).

The main distinction in status was that guidelines were advisory and normally complied with. This view was upheld by the majority of opinion leaders who said that clinical guidelines allowed practitioners more scope to exercise judgement and discretion. This view was encapsulated by a policy maker who observed …

> 'They are not rules, they are guidelines.'

Only one nurse in a policy influencing role described guidelines as …

> 'a little bit more prescriptive (than protocols) because I would assume they would be more evidence-based … they would be based on something from NICE or whatever.'

Just over half (19/35) of the opinion leaders connected guidelines with documents produced by national organisations, such as the National Institute for Health and Clinical Excellence (NICE) or professional bodies like the Royal College of Midwives (RCM). Guidelines were described as the most evidence-based approach because the recommendations are graded according to the best available research.

These finding about the advisory status of clinical guidelines reflects the commonly held understandings found both in the literature and in the public domain. Clinical guidelines are defined as systematically developed statements to assist practitioners in making decisions (Field & Lohr, 1990). They have been widely adopted as a tool to improve quality of care and aim to be explicitly evidence-based (Ketola, Kaila & Honkanen, 2007). Guidelines are considered particularly useful for junior staff who may lack the experience and/or knowledge in a given situation (Lawton and Parker, 1999). The term guideline is commonly defined as a guide that may be applied flexibly depending on individual differences and needs. For example, Gawlinki (1995) states that …

> 'guidelines are intended to be broader and more flexible than a protocol … guidelines can and should be tailored to fit individual patient needs … a guideline tells the practitioner that … "the majority of your patients will want this, but some will not. For important interventions you must consider the pros and cons' (p18-19).

Similarly the NICE website refers to clinical guidelines as evidence-based recommendations that are intended to help, but not replace the judgement of health professionals …

> 'Clinical guidelines are recommendations by NICE on the appropriate treatment and care of people with specific diseases and conditions within the NHS. They are based on the best available evidence. While clinical guidelines help health professionals in their work, they do not replace their knowledge and skills' (NICE website, 2008).

2.1.4 Care pathways

There was more agreement about the meaning of care pathways, with just over half of survey respondents defining them as activities or procedures that constitute the patient journey, although a further 40 per cent understood them to relate to a set of procedures, not necessarily to the whole journey. In contrast, all the opinion leaders defined care pathways as the whole journey for people with a specific condition, through the health

care organisation or across organisational boundaries, and often involving different professions.

Most survey respondents understood the status of care pathways to be advisory (43 per cent) or informative (40 per cent) with just over 10 per cent viewing them as mandatory. This reflects the views of the opinion leaders who also said that it was possible to deviate from a care pathway. Such variation, known as variance tracking is a distinct feature of integrated care pathways (Gray 2004). Variances are departures from the sequence of activities set out in the pathway and the reasons for such variations are recorded and monitored.

These findings accord with definitions of care pathways as multidisciplinary plans of care that are used as a guide to co-ordinate, deliver, review and document patient care found in the literature (e.g. Riches, Stead & Epsie, 1994; Layton, Moss & Morgan, 1998; Cheah, 2000). The European Pathway Association had a broad definition of care pathways that comprises the methodology, defining characteristic and aims. Care pathways are defined as …

> 'a methodology for the mutual decision making and organization of care for a well-defined group of patients during a well-defined period. Defining characteristics of care pathways include:
>
> an explicit statement of the goals and key elements of care based on evidence, best practice, and patient expectations; the facilitation of the communication, coordination of roles, and sequencing the activities of the multidisciplinary care team, patients and their relatives; the documentation, monitoring, and evaluation of variances and outcomes; and the identification of the appropriate resources. The aim of a care pathway is to enhance the quality of care by improving patient outcomes, promoting patient safety, increasing patient satisfaction, and optimizing the use of resources' (EPA 2005).

Pathways continue to feature in Department of Health policies albeit with different meanings. For example, the 'Urgent Care Pathway for Older People with Complex Needs' (DH 2007) summarises best clinical practice and suggests indicators for audit but does not outline the patient journey. The current review of the NHS, led by Lord Darzi, refers to eight specific patient care pathway groups as a way of categorising major user groups or interventions. There are clinical pathway groups for: maternity and newborn; children's health; staying healthy; long-term conditions; acute care; planned care; mental health; and, end of life care.

2.1.5 Algorithms and flowcharts

There was most uncertainty about the meaning of algorithms/flow charts with survey respondents equally likely to define them as a specific procedure, a set of procedures, part of the overall patient journey or none of these. Most respondents identified the status as informative (44 per cent) or advisory (28 per cent) although 15 per cent thought they were mandatory.

Although algorithms and flow charts were rarely mentioned as a 'decision tree' or decision making strategy (Offredy, 1998; Wu *et al*, 2005) they were a popular way of displaying the decision and action points for a protocol, pathway or guideline. For example, five of the 33 UK development/implementation studies used a flow diagram, a flow chart or an algorithm as an easy to follow format and user friendly tool. The algorithms in NICE guidelines were commended for their usability by some case study participants.

2.1.6 Nesting protocols and guidelines within pathways

Several opinion leaders with first hand experience of standardised care often discussed protocols and guidelines as being part of or 'nested' within care pathways. The following definition given by a practice development nurse illustrates the connection between the different forms of standardised care and new working practices …

'Guidelines are evidence-based, giving specific advice or instructions. Integrated pathways are on a longer continuum. They cover the whole patient journey, incorporating different professions and settings. Pathways comprise protocols and guidelines, whereas protocols are for specific actions and tasks that allow devolved or delegated decision-making. For example, they are linked to the extended roles of nurses and reduced hours for junior doctors.'

2.1.7 Conceptual confusion

The findings from the national survey reveal variations in understanding about the meaning and status of common forms of standardised care. Such differential understandings, especially about status, could have significant implications for practice, with the risk of errors potentially arising from misunderstandings. The confusion caused by language was identified as a concern by Johnson (2001) and Walkling-Lea (2004) who both comment about NHS staff being bombarded with new jargon, terms and buzz words. The problem is more than simple semantics because lack of clarity could compromise patient safety. Protocol-based care was another new concept, but one which had negative connotations for many opinion leaders, because of the association with a prescriptive, mandatory approach. It is important to remember that language may engender resistance and the risk of 'treatment by numbers'.

We introduced 'standardised care' as an inclusive term that captured the purpose of setting standards to reduce unacceptable variations but without the mandatory connotations. Also, because of the confusion and uncertainty about protocol-based care, a concept analysis (Rodgers & Knafl 2000) was undertaken early in the research to clarify, define and identify the distinct attributes of protocol-based/standardised care (Ilott *et a*l 2006).

2.1.8 Concept analysis

The concept analysis involved analysing the differences and similarities between the terms used in the literature, policy documents and by the opinion leaders. The results highlighted the qualitative differences between standardised care in specialist services and generic settings on a number of dimensions. These dimensions expose the nuances

of standardised care and serve to caution against a single, simplistic approach to this way of working.

The following definition was produced …

> '*The term protocol-based care may be applied in two ways:*
>
> *firstly, in generic settings where multi or uni disciplinary staff standardise clinical care processes*
>
> *secondly, in specialist settings where authority for clinical care processes is delegated to those working in expanded roles.*
>
> *In both contexts, staff follow rules codified in documents such as protocols, care pathways and clinical guidelines, which aim to standardise health care delivery and outcomes. These documents do this in subtly different ways, by varying the specificity and scope in which they have an effect upon the processes of clinical care. Staff retain responsibility for using them appropriately and for obtaining informed patient consent*' (Ilott *et al*, 2006 p550).

It is important to acknowledge that these two applications are archetypes and, in reality, the distinctions between specialist (role specific) and generic (routine care) settings are likely to be less clear cut. Each application is described on a number of dimensions to highlight some of the implications of the different meanings in specialist and generic settings.

Specialist (role specific) settings:

Definition: Refers to the modernisation of health care through service or workforce redesign which involves nurses, midwives or health visitors taking on new and expanded roles underpinned by standardised care.

Key features: In these specialist settings, decision making and specific tasks are delegated from medical practitioners to nurses or from midwives to midwifery care assistants, or from health visitors to nursery nurses, who adhere to task-focused protocols, having been trained and assessed as competent to do so.

Examples include NHS Direct, a nurse-run telephone advice service; walk-in centres for people with minor injuries; midwifery-led birthing centres for low risk women; nurse-run clinics in primary care to monitor diabetic patients; and nurse-led discharge from hospital.

Drivers: These changes in service delivery are reactions either to national policy such as government targets to reduce waiting times and to improve the treatment of people with chronic impairments or to financial incentives to achieve the standards set in the Quality and Outcomes Framework, the contract for general practitioners, by adjusting the skills mix in primary care. Workforce redesign is also an expedient response to comply with the European Working Time Directive with the consequent reduction in the working hours of junior doctors.

Change: There may be less resistance to change with staff recruited to a new service or to those motivated to learn and develop, to expand their scope of practice to reflect their experience and expertise in a speciality.

Implications: In specialist settings, staff may be more motivated as they choose to take on expanded roles or apply to work in new services. An alternative interpretation would be that nurses are then restricted to administering technical tasks within parameters set by others - by working to specific protocols - that do not allow holistic nursing practice and underestimate or ignore nursing knowledge.

Generic (routine care) settings:

Definition: Refers to using a model of standardised care within everyday practice. This means that nurses, midwives or health visitors are expected to implement some form of standardised care within their routine practice.

Key features: Standardised care is introduced into, and expected to be used within, everyday clinical care. It may be an additional component of care, a specialist aspect of care, a new way of doing something based upon a review of the evidence or in response to locally identified need, or it may document and thereby formalise existing practice.

Examples are guidelines for mouth care in an acute hospital, immunisation protocols in primary care and a care pathway for end of life care in nursing homes.

Drivers: Such a change in working practice may be a top-down imposition, a bottom-up initiative or a mixture of these approaches. For example, it may be an organisational response to a national directive, such as the clinical guidelines published by the National Institute for Health and Clinical Excellence; or the change may be instigated by staff in response to a specific incident; or motivated by a desire to introduce evidence-based practice. A hybrid of these approaches is when national guidance is discussed and then tailored to the local situation; or when standardised care developed in another health care organisation is adopted and then adapted to fit the local context.

Change: The problems of change and change management were highlighted by opinion leaders with direct experience of developing standardised care. Some opinion leaders queried whether these documents are actually used in practice and expressed disappointment when audit results confirmed their suspicions. The degree of, and response to change may be related to the sense of control of the drivers, especially whether it is a top-down imposed change; or a locally owned and developed innovation to improve patient care; or just formalising current practice which does not require any behaviour change.

Implications: A variety of attitudinal and organisational reasons for non-compliance were given. For example, opinion leaders described resistance to any change in working practices and antipathy towards standardised care. The main organisational reasons were staff shortages, lack of time, either for training or to deliver the improved standard of care, and workload pressures, especially if the change involved additional paperwork. Ownership and understanding, arising from contributing to the development stage, was considered to be important for acceptance and commitment to use standardised care by

most of the opinion leaders and case study participants, but this was difficult to achieve because of the work pressures on front-line staff.

2.1.9 Summary

This section has drawn upon different methods to clarify the meaning and status of standardised care. The findings corroborate differential understandings about the variants of standardised care. There was most consensus about protocols (as mandatory procedures) and least about algorithms/flow charts. The conceptual ambiguity and lack of consensus is a potential source of confusion and error. A concept analysis showed subtle distinctions between standardised care in specialist and generic settings, albeit as archetypes. This suggests that a simplistic approach to standardised care is unhelpful, especially when it serves multiple purposes. The purposes attributed to standardised care are examined in the next section.

2.2 Purposes of standardised care

This section draws upon and integrates information from interviews with 35 opinion leaders and the 33 UK studies appraised in the development/implementation systematic literature review. The findings provide a more nuanced and multidimensional understanding of the purposes of standardised care than that presented in policy documents. The purposes can be seen as operating at multiple levels (e.g., policy, organisational, team and individual level) and for different stakeholders (e.g., managers, practitioners, patients) with often considerable overlap between them. For example, there were perceived to be close links between the stated purposes of standardised care in policy documents and for health care organisations with each Trust being responsible for tailoring national policies to their local community.

Standardised care serves many purposes which relate to:

- Standards and standardisation;
- Evidence-based care;
- Clinical governance;
- Risk management;
- Cost and efficiency;
- Effective teamworking;
- Role expansion and nurse-led services; and
- Patient care and voice.

Each purpose is summarised in this section.

2.2.1 Standards and standardisation

The policy goal of standardised care is to increase the quality of care as *'doctors, therapists and nurses will increasingly work to standard protocols'* (DH 2000, p20).

It is unsurprising then that the purpose stated most frequently by the opinion leaders was standardisation or eliminating unacceptable variation in practice or inequity of service provision. Standardisation was defined and interpreted in a variety of ways by the ten opinion leaders who highlighted this purpose. For some it meant offering the same standard of care and reducing any variation by ensuring consistency of care and advice. As one medical practitioner said …

> '*I think that the benefits should be around standardisation of care.*'

Other aspects of standardisation were also important. These related to fairness, for equity of access to services for all patients and also for more equitable distribution of health care resources throughout the country. Standardisation applied at an organisation level: across Trusts, within one health community or between district general hospitals following tertiary protocols from specialist centres. A practice nurse, in a joint practice and policy influencing role, emphasised standardisation 'across the piece,' especially when defining and developing new roles …

> '*It's important that there are policies and standards that these nurses (modern matrons, community matrons) can follow because they are new developing roles and they do need, we do need to have practical protocols to follow, to ensure that again we're providing a high quality standard of care across the piece. Because they are new and developing roles some of their roles need to be defined via protocols.*'

The opinion leaders differed about the extent to which standardisation permitted variation in practice. Some said variation was difficult to justify for legal reasons whilst others expected variation, and for others, variation depended on the context. A medical practitioner with direct experience of developing protocols commented ..

> '*There is sometimes a slightly glib assumption that if we see variation in practice that's a bad thing and that shows that someone must be getting it wrong somewhere and therefore we need a protocol to make sure that that variation is removed … it still may not be appropriate, because it might be there are very good reasons for variation.*'

There were also different interpretations as to whether the standards related to setting a minimum standard of care or whether they were rules for standardising the quality of care. Seven opinion leaders, all from a variety of nursing backgrounds, mentioned the value of standards for audit and service evaluations. A health visitor observed …

> '*It is giving you something you can audit against, which is very helpful; you can actually evaluate the service.*'

Standardisation was also seen as a policy driven approach to encouraging change at an organization level, for example in readiness for electronic patient records or for controlling '*maverick practice*.' The impact on change management with national information technology software was commented upon by a policy maker, who said …

> '*You have a huge set of dilemmas … So the more you standardise the systems, the easier it was for the provider and the harder it was for the organisation that was having to use the system, because they would have to change their practices.*'

Standardised care as a means of controlling and regulating health care professionals' behaviour was also mentioned, but with the caveat about a degree of flexibility about their use. Two nurses and a medical practitioner stated the value of protocols for preventing staff '*going off on a whim*' …

> '*If you don't have a protocol; it gives nurses the authority to go off at a whim, to do as they please. You need to have a protocol as long as it is not too restrictive, as long as sometimes you can think as well.*'

The purpose of standards and standardisation was also prominent in the systematic literature review about development and implementation. Most studies described how nursing tasks and activities were standardised. For example, some of the included studies were about immunisation in primary care, weaning mechanically ventilated patients in intensive care units, topical negative pressure for wound healing in two acute hospitals, sedation in a children's surgery ward, oral care in a palliative care unit, management of constipation in a critical care unit and improving the documentation of care in a stroke rehabilitation unit.

Four of the 33 included studies had a remit to standardise services per se. There was a study about promoting the use of national guidelines for management of acute asthma in four GP practices, two out-of-hours services and two nurse-led walk-in centres. Another described standardising nursing care for patients with fractured neck of femur throughout a hospital. There was a report about improving the consistency of diagnosis and treatment of women with symphysis pubis dysfunction in primary and secondary care settings. The fourth study described introducing the Liverpool end of life care pathway into two primary care trusts.

2.2.2 Evidence-based care

Guidelines, pathways and protocols were identified as a key mechanism for getting research evidence into everyday practice by many of the opinion leaders, reflecting the embedded research model (Nutley, Walter & Davies, 2007) that is gaining popularity in nursing (Gerrish *et al* 2008).

A defining feature of documents that are intended to standardise care it that they are described as 'evidence-based' meaning that they are underpinned by the best research and/or expert opinion and/or best practice. They support the quality and modernisation agenda through implementing NICE guidance and National Service Frameworks at a local level. This purpose was noted by a nurse, who observed …

> '*I think it is central to multidisciplinary effort that will improve things for residents or patients and gives the practitioner, whichever setting they're working in, the confidence of knowing that they're working to evidence-based practice.*'

Although nearly half the studies in the literature review (15/33) were about improving the quality of patient care, the link with evidence-based care was often not explicit. This may have been due to the publication dates, with just over half (18/33) being published before 2002. However, less than half (13/33) made reference to a literature review and none referred to a librarian/information specialist.

2.2.3 Clinical governance

Clinical governance is an important way of improving the quality, safety and effectiveness of health care. Risk management and clinical effectiveness are two elements of clinical governance. Standardised care was perceived by some opinion leaders as a mechanism to support clinical governance. A nurse researcher illustrated this point, saying …

> *'I think it is around the clinical governance agenda which is linked to protection…* *minimising risk for the patient in terms of their care experience. So, it is about trying* *to establish a standard of care that patients will receive that is evidence-based. It has* *to do with accountability to the patient and reducing risk.'*

2.2.4 Risk management

Different aspects of risk were mentioned by nearly half (15/35) of the opinion leaders. Protocols were described as a risk management tool for Trusts because they specified clinical care processes and improved record keeping. Standardised care was seen as a tool to protect against the increased willingness of the public to complain and the rising level of litigation. It provides a safety net for staff taking on expanded roles or responding to changes in skills mix, but only if standardised care, supported and did not replace, clinical judgment. Other aspects of risk management included:

- avoiding errors;
- reducing complaints and litigation;
- managing clinical risks; and
- improving safety.

2.2.5 Cost and efficiency

Although cost control and increased efficiency are commonly cited purposes of standardised care in North America (Beyea 1996; Greenhalgh *et al* 2004) only one opinion leader, working in joint academic and practice post, stated that standardised care was linked to the drive to make savings and reduce the cost of health care.

A few studies (5/33) in the development/implementation systematic literature review studies gave cost and/or efficiency reasons for standardised care in nursing, midwifery and health visiting. These were aimed at coping with increased demand, reducing costs, and freeing nursing time or doctors for others tasks, with nurses expanding their scope of practice.

2.2.6 Teamworking

Policy and guidance documents (e.g., The NHS Plan (DH 2000) and MA/NICE 2002) promote standardised care as a way of improving team work across professional and organisational boundaries, and also for making '*the best use of all the talents of NHS staff'* (DH 2000, p83). The utility of standardised care for promoting multi-disciplinary teamwork was broadly supported by a number of opinion leaders. Standardised care and

teamwork was raised by nine nurses and two medical practitioners (11/35) who said protocols, guidelines and pathways enhanced teamwork between medical consultants, nurses and other agencies, in areas such as communication, the consistency and co-ordination of care. For example, standardised care was perceived as promoting a common language across team members and therefore improving communication.

The purposes related to teamwork were said to be achieved through a number of means, including discussions, when developing the protocol, by giving role clarity about 'who should do what, when and how' and with improved documentation and sharing of information. A nurse with previous indirect experience as a manager portrayed standardised care at the level of teamwork in the following terms …

> *'It is giving multi-disciplinary teams a more common language and the opportunity to talk about things because if you don't, you never can be clear can you? One assumes everybody thinks the same but they don't unless you actually have the conversation. People are working now much more in multi-disciplinary teams. It is amazing how people do enjoy developing a protocol - even when they often tell you … "'oh we really work as a team but we never talk to each other about what we're doing".'*

Nine of the 33 included papers in the systematic literature review identified team level reasons for the developing and implementing standardised care in nursing, midwifery and health visiting. The purposes included to improve working relationships, to eliminate inconsistencies in care, to formalise prevention and aftercare and to standardise treatment or to set standards within the team.

Interestingly, there was less agreement amongst the survey respondents about the teamwork. Only 50 per cent agreed or strongly agreed with the statement that standardised care promotes effective multi-disciplinary teamwork with one in five disagreeing or strongly disagreeing with this statement. Similar, inconsistent findings about teamwork and integrated care pathways were reported in the literature and in a case study exploring the effectiveness of care pathways in facilitating integration in community-based teams (Huby & Rees, 2005).

(See also the discussion in chapter one which highlights cultural differences between professions which can lead to friction in the multi-disciplinary team over use of standardised care.)

2.2.7 Role expansion and nurse-led services

Service modernisation and workforce redesign (DH, 1999: DH, 2000) has strengthened the nursing, midwifery and health visiting contribution to health care by promoting nurse-led services and the expansion of nurse roles in assessing and diagnosis, prescribing and discharging patients. Standardised care was seen by some opinion leaders as a necessary requirement to support this expansion, serving to define safe and best practice. As one practice nurse, with direct experience of developing standardised care, acknowledged …

> *'with those new and developing roles … it is important to have protocols around those areas.'*

The introduction of standardised care to support the extension of the nurse's role was strongly supported in the systematic literature review. Almost half (16/33) the included studies were about workforce redesign, role expansion or nurse-led services. In seven studies, the development of standardised care was portrayed as facilitating a nurse-led service, five of which dealt with out-patients. In these nurse-led services, standardised care permitted nurses to treat minor injuries in casualty units in community hospitals; to diagnose and treat DVT in a new out-patient setting; to manage idiopathic anal fissure in a colorectal clinic; to run a fast track iron deficiency anaemia clinic in an endoscopy unit and a fracture review clinic in an orthopaedic department. Two studies involved in-patients, with nurses managing pre-operative optimisation in an intensive care unit and nurse-led chest drain removal in a cardiac high dependency unit. Three studies described expanding the scope of nursing practice, with two relating to district nurses and the third was about the development of a nurse practitioner role, carrying out flexible cystoscopy in a day case unit. Ten studies referred to nurses prescribing or administering drugs; two of these were located in nurse-led services - in a day care dermatology unit and in a glaucoma triage assessment clinic.

One of the key purposes of protocol-based care, as stated in The NHS Plan was that it would …

> *'make the best use of all the talents of the NHS staff'* (2000, p83).

A quarter of the survey respondents disagreed or strongly disagreed that standardised care helps make the best use of staff skills and knowledge. Less than 40 per cent agreed with this statement. Chapters six and seven explore the impact of standardised care on the skills and knowledge of nurses, midwives and health visitors in greater depth.

2.2.8 Patient care and patient voice

Although the MA/NICE Guidance states that …

> *'involving patients is essential in planning service improvements'* (2002, p5)

only one study reported doing so, giving patients a voice in the decision-making process. This was a protocol instigated by a patient representative support group to improve the consistency of diagnosis and treatment of women with symphysis pubis dysfunction.

Ten opinion leaders (10/35) thought that improving patient care was a primary reason for standardising care. Patients were said to be receiving evidence-based treatment that minimises risk and makes staff accountable for the best care and outcomes. A nurse researcher in a joint academic/practice post and with first hand experience of developing protocols commented …

> *'I like to see it (standardised care) as a way of really achieving a gold standard for a patient.'*

Equity was another purpose mentioned earlier in relation to standardisation (see section 2.2.1). This meant that patients knew that they were receiving the same treatment as everyone else because this was stated in the standards, especially if this was explained. Equity and fairness were highlighted in the nursing case study about the myocardial

infarction care pathway and all three health visitor case studies about maternal mental health.

A few opinion leaders expressed reservations, saying that standardisation was counter to the notion of individual care and restricted patient choice by limiting the care options available. A midwife with direct experience observed that …

> *'Individualised care has to take account of what the individual wants and it may not fit in with the standard. I guess that is where the clinical judgement might have to come in and making sure that the standard is high enough to meet the women's wants and needs.'*

The purpose of improving patient care was corroborated in the development/ implementation systematic review, with this reason mentioned in nearly half (15/33) of the included UK studies. The reasons ranged from health promotion by increasing the immunisation rate; through the safety and effectiveness of specific clinical procedures; to reducing the stress on newly bereaved carers, improving patient motivation and satisfaction and reducing delays and discomfort. These reasons mirror the professional pull factors described in chapter five as the rationale for nurses, midwives and health visitors contributing to the development of standardised care.

2.2.9 Summary

This section highlights the multiple purposes of standardised care. The perceptions of the opinion leaders, supported by the systematic literature review, corroborated that the purposes of standardised care has a strong emphasis on quality, standardisation and clinical effectiveness. This was seen to be achieved through reducing unacceptable variation in practice, implementing evidence-based care, risk management, and providing staff with a tool to define best practice. Some concern was expressed where conformity and 'proceduralisation' were seen as overly driven by risk-management.

Most opinion leaders, case study participants and the practitioner knowledge reported in the literature review emphasised the positive purposes of standardised care, in that this way of working supports effective, quality health care. However, it must be borne in mind that the samples for the interviews and survey were relatively small in relation to the population of nurses, midwives and health visitor in the UK; and also that most studies in the review drew upon practitioner knowledge as there were few quality research studies about standardised care. Also, the participants could have comprised more enthusiasts than in the general population of nurses, midwives and health visitors, especially as most had a vested interest and ownership of 'their' standardised care. Chapters six and seven redress this limitation to some extent by considering the negative impact of standardised care.

The voice of patients was notable by its absence, even though current policy is promoting patient choice and control through a personalised health service (Darzi 2007) and it was encouraged in the guidance (MA/NICE 2002). It has been argued that standardised care is a tool for increasing patient and carer involvement (MA/NICE 2002), however, this was only touched upon in relation to better professional-patient communication. Interestingly, patient involvement in the development and implementation of standardised care was limited in the systematic literature review, the

opinion leader interviews and the case studies, to examples involving the ante and post natal health of women.

2.3 Conclusion

Clarity of understanding about the meaning and status of different forms of standardised care would seem to be a pre-requisite for safe, effective implementation of this way of working. Although there were varying degrees of agreement, unanimity was not gained from any group of informants or by any of the methods. There was most agreement about the mandatory status of protocols and the advisory status of clinical guidelines; and some consensus that protocols meant specific procedures and care pathways referred to the patient journey. In response to the conceptual ambiguity, a concept analysis was done to clarify and define protocol-based care. This highlighted the archetypal differences between standardised care in specialist and generic settings on a number of dimensions.

The multiple purposes of standardised care, expressed in policy documents and by the research participants, adds to the complexity of understanding. Although the primary purpose is setting evidence-based standards to promote quality and standardising services to reduce unacceptable variations, there are a range of other purposes, operating at organisational, team, staff and patient levels.

This chapter has given a macro level overview of the meaning, status and purposes of standardised care. In the next chapter, the focus shifts to the micro level with an examination of the settings where standardised care is used, the extent of use in care delivery by nurses, midwives and health visitors, and the clinical tasks or situations that are standardised.

3 Standardised care in the NHS: Current use

A primary aim of this research was to identify the settings within the NHS into which standardised care has been introduced. In this chapter, information is drawn from the national survey, the opinion leader interviews, the systematic literature review and the case studies to show the prevalence of standardised care in many different health care settings. In addition, the findings about who uses standardised care, and for what care processes, are presented to give a rounded picture of standardised care in current practice.

Standardised care is an umbrella term covering protocols, procedures, integrated care pathways, clinical practice guidelines, algorithms, flow charts, policies, standards and care bundles. The differences and similarities between these variants and the inter-changeable, context-specific terminology were discussed in chapter two. In this part, standardised care is used as the generic term, except where the data refers to a specific model, such as integrated care pathways.

In chapter 3:

Section 3.1 presents findings from the national survey regarding the use of standardised care across different types of employers, fields of practice, professional groups and activities.

Section 3.2 examines the evidence regarding the different settings where standardised care is used, drawing upon the findings from the literature review.

Section 3.3 draws upon the findings from the opinion leader interviews and the case studies to discuss the types of situations or tasks that may be more amenable to standardisation.

3.1 Survey evidence about settings

All the sources of information show that standardised care is widespread, used in primary, secondary and tertiary care settings as well as in both established and new services. The national survey confirms that standardised care is used in primary and secondary care settings by many front-line nurses, midwives and health visitors, and also, that most care is delivered in accordance with standardised care.

From the 2,711 respondents, the majority were front-line practitioners working predominantly in NHS Hospitals (64%), followed by NHS Community (14.5%) and Primary Care Trusts (8.4%) (see Appendix 3a for a detailed description of the sample characteristics).

3.1.1 Use across different employers

Table 3.1 gives a breakdown of the most frequently used form of standardised care across different types of employers.

Table 3.1 Form of standardised care used most frequently by employer

Employer type	Protocols (%)	Clinical guidelines (%)	Care pathways (%)	Flowcharts (%)	None of these (%)	N
NHS Hospital	37.8	51.1	8.1	2.2	0.6	1633
NHS Community	30.2	54.7	9.2	3.4	2.5	358
NHS Direct	0	0	0	100	0	1
NHS Other	45.0	25.0	25.0	5.0	0	20
GP Practice	37.6	58.1	1.1	2.1	1.1	93
Health Authority/NHS Executive	11.1	55.5	22.2	11.2	0	9
Independent Hospital	24.2	24.2	45.6	3.0	3.0	33
Care Home	22.2	59.3	18.5	0	0	54
Other independent	40.0	25.0	5.0	10.0	20.0	20
Bank/Agency	39.1	56.5	4.4	0	0	23
Higher Education	28.6	64.3	7.1	0	0	14
Hospice/Charity	26.0	44.4	29.6	0	0	27
School	50.0	50.0	0	0	0	2
Primary Care Trust	32.8	51.0	12.6	3.0	0.6	198
Other Health Employer	41.7	50.0	8.3	0	0	12
Use across sample (%)	35.6	51.3	9.5	2.5	1.0	2497

Specifically, 51.3% of the sample report using guidelines most frequently, followed by protocols (35.6%) and care pathways (9.5%). Clinical guidelines and protocols are prevalent across primary and secondary care and across public, private and charitable

sectors. The only exception is independent hospitals where care pathways are used most frequently (45.6%) compared to protocols and guidelines (24.2% in both cases). Interestingly, 20% of respondents who worked in 'other independent' sector reported that they did not use protocols, clinical guidelines, care pathways or flow charts.

3.1.2 Use in different fields of practice

Table 3.2 gives details about the use of different forms of standardised care across different fields of practice.

Table 3.2 Form of standardised care used most frequently across different fields of practice

Field of practice	Protocols (%)	Clinical guidelines (%)	Care Pathways (%)	Flow charts (%)	None of these (%)	N
Midwifery/Women's Health	38.0	57.0	3.0	1.2	0.8	1324
Primary Care	40.0	50.0	6.6	2.9	0.5	208
Adult General	26.1	41.6	28.0	4.3	0	161
Children & Families	36.9	47.7	8.7	4.7	2.0	149
Community Care	27.1	52.3	12.1	4.8	3.7	107
Older people nursing	29.6	49.4	17.3	3.7	0	81
Adult Critical Care	39.4	34.8	18.2	7.6	0	66
Mental Health	13.5	59.6	23.1	0	3.8	52
Paediatrics	40.8	40.8	10.2	4.1	4.1	49
Oncology/palliative care	28.2	43.6	28.2	0	0	39
Learning disabilities	36.0	40.0	24.0	0	0	25
Rehab/Longer term	33.3	33.3	33.4	0	0	15
Use across sample (%)	35.8	52.5	8.5	2.2	1.0	2276

This shows that clinical guidelines are used most frequently across most fields of practice (52.5%), followed by protocols (35.8%) and care pathways (8.5%). Interestingly, in adult critical care protocols appear to be used most frequently whereas in paediatrics and rehabilitation protocols and clinical guidelines are used with the same frequency.

3.1.3 Use by different professional groups

Table 3.3 provides information on the use of standardised care to deliver patient care across the whole sample including different professional groups.

Table 3.3 Use of standardised care across professional groups

Professional group	Amount of patient care using standardised care			
	None / A little direct care (%)	Some of direct care (%)	Most/All of direct care (%)	N
Staff Nurse	6.4	27.0	66.6	392
Community Nurse	13.1	37.7	49.2	61
Community Midwife	3.8	26.2	70.0	393
Sister/ward manager	4.2	32.1	63.7	193
Practice Nurse	3.7	18.5	77.8	81
District Nurse	5.3	57.9	36.8	19
School Nurse	4.5	40.9	54.5	22
Nurse Practitioner	22.3	18.5	59.3	54
Senior Nurse/midwife matron	2.9	36.2	60.9	174
Hospital midwife	2.8	24.4	72.8	672
Health Visitor	12.1	39.3	48.6	173
Manager /Director	23.7	28.9	47.4	38
Researcher/Lecturer	16.7	33.3	50.0	30
Clinical Specialist	10.5	27.9	61.6	86
Use across sample (%)	5.9	28.4	65.7	2388

The findings show that two thirds of the sample use standardised care to deliver most or all of patient care whilst a quarter of respondents use standardised care to deliver some

of patient care. Only 5.9% of the sample reported not using standardised care or using it to a small degree. Table 3.3 also shows the prevalence of standardised care across both junior (e.g. staff nurses) and senior staff (nurse practitioners/senior nurse/midwife matron).

3.1.4 Use across different care activities

Standardised care is used for the full range of nursing, midwifery and health visiting activities. Almost two thirds of survey respondents reported using standardised care 'most or all of the time' for common activities such as assessment and interventions. These are shown in table 3.4 presents information on the types of activities where standardised care is used.

Table 3.4 Use of standardised care across different activities

Type of activity	Never/ Seldom (%)	Some of the time (%)	Most/All of the time (%)	Not applicable (%)
Health screening	6.8	10.2	63.0	20.1
Assessment	2.6	12.6	79.0	5.6
Intervention	2.3	14.6	76.0	7.0
Prescribing	10.5	5.4	48.6	35.4
Patient education	8.9	22.2	60.6	8.2
Discharge	7.0	10.7	60.8	21.3

N=2,711

It can be seen that standardised care is used for a range of activities. These included assessment (79%), intervention (76%), health screening (63%), discharge (60.8%), patient education (60.6%) and prescribing (48.6%). Just over a third of respondents (35.4%) reported that prescribing was 'not applicable' suggesting that they did not use standardised care to carry out prescribing activities. These findings were also observed when examining separately nurses, midwives and health visitors' responses. However, unlike midwives and health visitors, just over a third of nurses (36.7%) indicated that they 'never' or 'seldom' used standardised care for prescribing.

3.2 Literature review evidence about settings

The survey findings show that standardised care seems to be ubiquitous in hospital and community settings, with much of nursing, midwifery and health visiting being delivered in accordance with clinical guidelines and/or protocols. This finding was corroborated by the other methods which added a more nuanced understanding of the settings where nurses, midwives and health visitors are involved in the development and implementation of standardised care. For example, 20 of the 33 UK studies in the

development/implementation systematic literature review were based in hospital wards, units or out-patient clinics. Of these five were in intensive care/high dependency units; two were in Casualty/Accident & Emergency Departments; and seven were in primary care (including one in a GP fund holding practice, one in two primary care trusts and one in NHS Direct). One paper did not specify the organisation whist nine were based in more than one setting. Four studies were based in nurse-led services which included a day care dermatology unit, a fracture review clinic, a glaucoma triage assessment clinic and a nurse-led clinic in an endoscopy unit.

In relation to the variants of standardised care, Currie (1998) conducted a postal survey of all NHS trusts to quantify the use of care pathways in the United Kingdom. She reported that 86% of Trusts were developing, piloting or using pathways and that the top five topics were fractured neck of femur (31%), stroke (29%), myocardial infarction (23%), hip replacement (23%) and asthma (12%). Further, Van Herck, Vanhaecht and Sermeus (2004) in a review of 200 papers published between 2000-2002, report that 48% of care pathways were developed for surgery, 26% related to medical conditions such as asthma and stroke, 5% were about rehabilitation, 4% covered psychiatry and 3% dealt with emergency medicine. In a recent critical appraisal of care pathway evaluation research, El Baz *et al* (2007) report that the most studied categories in the 115 included papers published between 1995-2005, were about cardiovascular surgery and cardiovascular diseases (17.4%), gastrointestinal surgery and diseases (16.5%), respiratory diseases, therapy and thoracic surgery (15.6%) and then orthopaedic diseases and surgery (11.3%). To our knowledge, similar review studies on the prevalence and settings where clinical guidelines or protocols have been introduced have not been carried out. Integrated care pathways may have attracted particular attention as a distinct form of standardised care because there is a dedicated journal and a European Association that promotes their use.

The following section draws on the opinion leader interviews, the case studies and the health care and organisational literature to examine the situations or tasks that may be more amenable to standardised care.

3.3 What situations or tasks may be usefully standardised?

3.3.1 Routine, predictable situations

Not all tasks and situations are equally amenable to standardisation. There was agreement between the opinion leaders and case study participants that standardised care is particularly useful for routine, predictable tasks. This view corresponds with prescriptions in the health care literature. For example, Greenhalgh *et al* (2004), reviewing the integrated care pathway literature, noted that pathways operate most effectively for patients when care and treatment follow a defined path, such as elective surgery in the acute setting, and less effectively when there is a greater individualisation and/or variation in the course of the episode.

Opinion leaders and case study participants identified patients with complex, multiple problems, or uncertain diagnosis as less well served by standardised care. This view has also been reported in the literature. For example, Boyd *et al* (2005) appraised guidelines

for elderly people, reporting that they focused upon a single problem and when they were reviewed together in the context of the multiple problems experienced by older people, the guidelines gave contradictory recommendations. Jones (1999) argued that care pathways were 'too simplistic to capture the essence of mental health work' (p336) particularly the unpredictability of chronic, relapsing psychotic conditions. In two reviews of care pathways there were very few about mental health, with Van Herck, Vanhaecht & Sermeus (2004) including 4% that covered psychiatry and El Baz *et al* (2007) including only 1.8%. This theme was also evident in the views of an opinion leader, a health visitor in a policy influencing role, who observed that that complex, community level health promoting interventions were not amenable to standardisation because they were developed in response to a specific needs assessment for a particular population.

This is not to say that all forms of standardised care are ineffective in more complex and unpredictable situations. Guidelines, care pathways and the like can still be useful as prompts that set out broad processes and goals, rather than outlining the detail of treatment (Greenhalgh *et al*, 2004). Greater complexity and variety requires correspondingly greater latitude for staff to use their knowledge, judgement, and intuition to determine the appropriate course of action. A strategic level interviewee at one of the case studies described the importance of intuition and tacit knowledge when dealing with uncertain situations …

> *'An awful lot comes from a sixth sense, a feeling that you can't distil. It is putting everything together and looking at the patient as a person … you consider other factors, for example a feeling that someone is deteriorating rather than following the readings because the monitor isn't attached properly'.*

The literature review and opinion leader interviews highlighted that standardised care is used for predictable tasks and processes within the context of expanded roles of nurses and midwives. In this context, protocols clearly state the boundaries of decision-making and action.

3.3.2 Scientifically robust evidence

Opinion leaders and case study participants proposed that standardised care is most appropriate for procedures underpinned by evidence that is scientifically robust. This perspective is probably self-evident and is supported by the evidence-based practice and standardised care literature (e.g., Lawton & Parker, 1999). Whether the document is based upon robust, stable, incontrovertible evidence will also impact on its successful implementation (Kitson *et al.*, 2008).

3.3.3 Uncommon events or emergency situations

A number of the opinion leaders felt that standardised care was a particularly useful tool for facilitating prompt, effective management of rare, emergency or high risk situations by all staff (regardless of profession, seniority or experience). Most of the examples related to acute situations where it is essential for individuals and the team to 'get it right first time.' This was epitomised by a medical practitioner, with direct experience, speaking about cardiac life support guidelines in the context of teamwork …

'A well trained team where everybody has been on their cardiac life support (course) is just a joy to behold, because everybody knows what is going on, everybody gets on with their job, and communication is facilitated.'

3.4 Summary

Standardised care is central to the work of the majority of nurses, midwives and health visitors working in primary and secondary care settings where these documents underpin the full range of clinical processes. They are reported to be particularly useful for routine, predictable situations, where the evidence is incontrovertible and for uncommon or emergency situations. The importance of discretion and flexibility, to ensure that standardised care is used appropriately, are discussed in more detail in chapters s five and six.

4 Developing standardised care: processes and roles

The second aim for this research was to examine the ways that nurses, midwives and health visitors contribute to standardised care. In this chapter two aspects of involvement are discussed. These are:

- The range of roles, tasks and activities involved in the development and implementation of standardised care.

- The evidence about the contribution of nurses, midwives and health visitors.

The chapter draws on evidence from the development/implementation systematic literature review, opinion leader interviews, the national survey and the cases studies to identify what is known, and also to report the current experiences of nurses, midwives and health visitors involved in the development process that goes from instigation to audit and review.

In Chapter 4:

Section 4.1 introduces UK data from the systematic review about the involvement of nurses, midwives and health visitors in the development process. Data from the review is analysed against the 12-step guidance produced by the Modernisation Agency (MA/NICE 2002). The findings show the range of activities undertaken as well as how the involvement of these staff groups is portrayed in the literature.

Section 4.2 presents the findings from the national survey that show the prevalence of involvement of nurses, midwives and health visitors in the standardised care process.

Section 4.3 uses findings from the opinion leader interviews and case studies to explore the nature of the roles adopted in development, including leadership and the direct and indirect involvement of front-line staff as end uses of the standardised care.

Section 4.4 identifies 'pull' factors that influence the participation of nurses, midwives and health visitors in development and implementation.

Section 4.5 summarises the barriers of time, financial resources and staff shortages which influence the involvement of these staff groups in the development process.

Section 4.6 summarises the evidence on involvement in implementation and development. It also highlights other factors in process in relation to the adoption of standardised care by other members of the team, organisational factors and sustainability, all of which are discussed in chapter five.

4.1 Development and implementation: literature review

In March 2005 electronic searches were undertaken of five nursing databases using a combination of the search terms 'protocols', 'guidelines' and 'care pathways'. This generated 6,648 potentially relevant titles and abstracts. Titles and abstracts were sifted against inclusion and exclusion criteria developed to identify articles which reported on the development or implementation of a form of standardised care and contained data specific to the involvement of nurses, midwives and health visitors.

A total of 319 papers were ultimately assessed to be of relevance to the research, of these 117 were based in the UK. The papers contain studies in nursing, midwifery and health visiting, and primary and secondary health care settings in the UK and were published between 1991 and 2006.

Most papers were not, and did not purport to be research. Rather, they represent context specific, practitioner knowledge (Pawson *et al* 2003) about the everyday experience of developing standardised care. Many were written by practising nurses who wished to share their experience via a nursing journal.

Data extraction revealed that the overall quality of data contained in these relevant papers was relatively poor. Although in some, a rigorous evaluation of the development and implementation process may have been reported on in terms of other outcomes (such as safety), the data relating to the input of nurses, midwives and health visitors might at best only be anecdotal. The exercise revealed that the evidence base about the involvement on nurses, midwives and health visitors in the development and implementation of standardised care in this context is limited and weak in nature.

The data did not support a full data extraction process. To provide an insight into development and implementation in practice, a representative sample of 33 of the 117 UK papers (33) was analysed against an existing development framework (MA/NICE, 2002). This helped to illustrate the range of roles and activities which are generally involved in the development of standardized care and provide narrative about whether these approaches are reflected in its development and implementation as reported in the UK. Details of the method and evidence tables are in appendix 2.

4.1.1 The 12-step guide to the development process

In 2002, the NHS Modernisation Agency and National Institute for Clinical Excellence produced a 12-step guide to developing and implementing protocols as *…*

> *'one option for a step-by-step approach towards development and implementation'* (MA/NICE 2002, p2).

The 12-steps are outlined in figure 4.1 and further details can be found in appendix 2b.

The framework is used here to illustrate the range of possible tasks and activities involved in developing and implementing standardised care. Data was extracted from the sample of 33 UK studies based on this framework to identify the extent to which nurses, midwives and health visitors are engaged in these activities and findings are summarised for each phase.

Figure 4.1: Twelve steps for development, implementation and review of protocol based care (MA/NICE 2002).
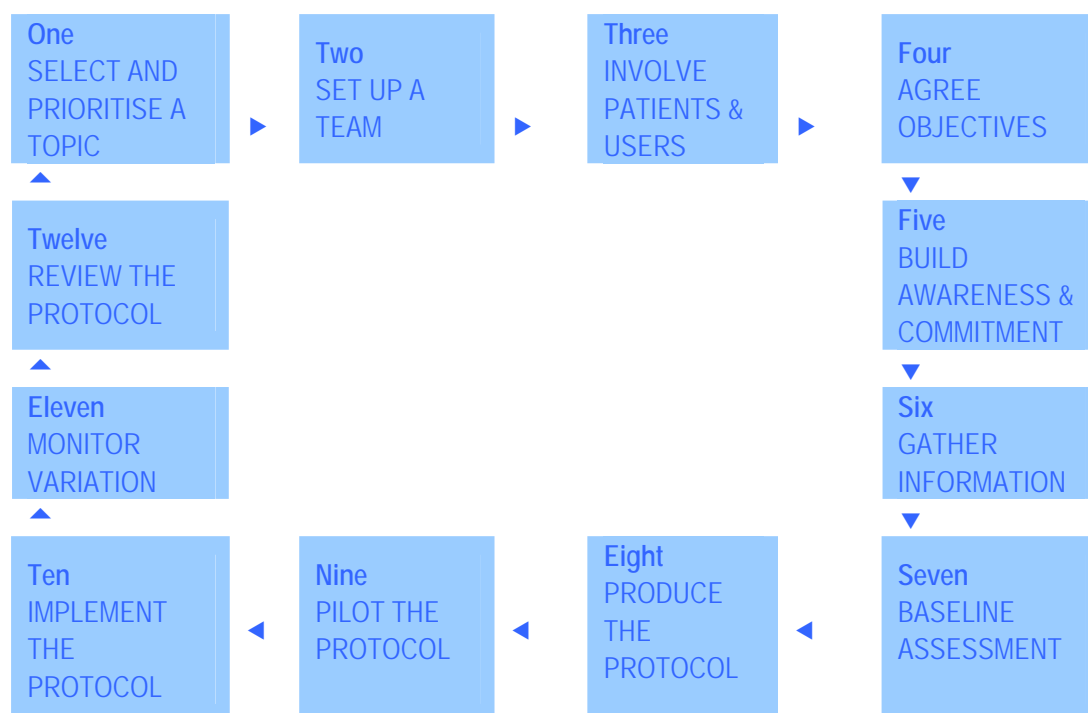
4.1.2 Findings using the twelve-step process

STEP 1

SELECT AND PRIORITISE A TOPIC

Main activities
- Select topics linked to national standards (NSFs, NICE) and local service needs
- Prioritise predictable, standardised, large volume, very high cost procedures and high risk diseases and care process
- Develop disease-based, problem-based, treatment-based and client-based protocols

All the studies gave the rationale for the instigating the standardised care. In the majority of studies (28/33) the priority topic was a response to local need. Only five studies highlighted national imperatives. These related to reducing waiting times, meeting the standards set in a national guideline, supporting the extended role of Emergency Nurse Practitioners and NHS Direct reducing demand on out-of-hours GP services and A&E Departments.

The purposes stated related to policy, patient, organisational, team, staff and task outcomes:

Modernisation: Almost half (16/33) related to modernisation through workforce redesign, role expansion or nurse-led services.

Standardising tasks: Many studies described standardising specific clinical procedures or tasks (see section 2.2.1).

Standardising services: Four studies had a broader, service-wide standardisation remit (see section 2.2.1).

Patient care: Improving the quality of patient care or the patient experience was the reason given in nearly half the studies (15/33).

Organisational reasons: A number of organisational reasons for developing standardised care were given in a third of the papers (10/33). These included such issues as increasing capacity, reducing costs, or developing new nurse-led services.

Teamwork: Reasons related to teamwork were cited by just under a third of the sample (10/33) and included aims such as to improve working relationships or to setting standards within the team.

By far the majority of articles in this sample (26/33) stated two or more purposes or reasons for selecting for developing and implementing standardised care into a specific context or a staff role, reflecting the multiple purposes discussed in chapter 2.

STEP 2 SET UP A TEAM	**Main activities** • Multi-disciplinary group of clinical and non-clinical staff • Agree terms of reference, a communication plan, a project plan, a meeting schedule and an implementation plan • 3-6 months from start to implementation

Only twelve studies reported that a team was established to develop the standardised care. In ten studies there was not any information about establishing a team or working group.

Multi-disciplinary team: Nearly a third (10/33) stated that a multi-disciplinary team was responsible for developing the standardised care. In four of these, the team comprised nurses and medical practitioners only. In the remainder, team members included a mixture of general practitioners, surgical staff, allied health professionals, a business manager, a child psychologist, the infection control team and a pharmacist.

Team leadership and membership: Team leadership was noted in only one paper where the team was led by a research physiotherapist. One team had a user/women representative.

Just over half the studies (16/33) reported the involvement of qualified nurses in the development and/or use of standardised care. In five studies, the grade, experience or training, as pre-requisites for nursing staff to be able to use the standardised care, was noted.

There were numerous titles for registered nurses that reflected their speciality and seniority. For example, palliative care nurses, intensive care nurses, paediatric nurses, vascular nurse specialists, senior casualty nurses, urology nurse practitioners, nurse practitioners, emergency nurse practitioners, ophthalmic staff nurses, nurse specialist.

Duration: The time taken to develop standardised care was noted in 10 studies. Only one study gave a detailed time frame, reporting the development of 29 care pathway protocols over a two month period as part of the Hazard Analysis Critical Control Points

approach in response to an infection control problem. The other nine studies gave general time frames which ranged from six months to three years with an average of 15 months. One study reported regular review meetings, stating that it was a year before the protocol was embedded in practice.

STEP 3 INVOLVE PATIENTS AND USERS	**Main activities** • Involve patient representatives and interest groups on the development team • Produce a summary of the protocol for patients

Although the MA/NICE Guidance states that 'involving patients is essential in planning service improvements' (2002, p5) only one study reported involving patients in the decision-making process. This was a protocol that was instigated by the patient representative support group.

Six studies described producing patient information leaflets as part of the implementation strategy.

STEP 4 AGREE OBJECTIVES	**Main activities** • Set clear, specific and measurable objective • Identify problems or barriers from both staff and patient perspectives

Nearly half (16/33) the studies reported agreeing aims or objectives for the development project or standardised care, including one that reported using audit results to produce a business plan for the Trust Board. The aims or objectives were included in 11 of these papers. This step in the development process was not mentioned in 14 papers. It was inferred from statements about when aims were agreed or how they were developed though discussion in the remaining papers.

STEP 5 BUILD AWARENESS AND COMMITMENT	**Main activities** • Gain strategic and clinical commitment by engaging stakeholders • Raise awareness and promote the benefits of standardised care

A variety of stakeholders and ways of gaining their support were described. Seventeen studies reported consulting, negotiating and discussing with members of the multi-disciplinary team. Eight mentioned medical consultants or general practitioners. Two

studies referred to relevant stakeholders. Five reported raising awareness by circulating drafts of the protocol to gain feedback.

STEP 6 GATHER INFORMATION	**Main activities** • Gather evidence of good practice, other organisations' experience and protocols, the views of patients, and the organisation's business plan and service objectives

Most studies (18/33) reported gathering information although this stage was not mentioned in 13 studies. Eleven studies gleaned information from more than one source, for example reviewing current literature, gaining local expert opinion and using a telephone survey to consult colleagues on other units.

Methods: The three most frequently mentioned methods were reviewing the literature/research (13/33), a questionnaire survey (5/33) and audit (4/33). Most of the nine studies that referred to a literature review did so in vague terms. Only four gave details of the databases searched with summary findings. None mentioned using a librarian/information specialist to assist with the search process.

STEP 7 BASELINE ASSESSMENT	**Main activities** • Map care process using case notes, interviews and group sessions • Identify who should see what information about patients

Over half the studies (19/33) did not mention a baseline assessment and none referred to the process of mapping care or information sharing proposals. One study described an exploratory clinical audit that used 80 decision points.

Thirteen studies reported obtaining baseline information. Audit was mentioned in six studies. Reviewing patient notes or outcomes was noted in three studies. Other methods included joint re-assessment of patients' collection of baseline data at three time points to assess the feasibility and impact of a new district nurse-led service, a postal survey of service users and an investigation of infection control procedures.

STEP 8 PRODUCE THE PROTOCOL	**Main activities** • Agree the format as a single care record • Check the content meets the criteria • Gain corporate level approval before piloting the protocol.

Although half the studies (16/33) gave information about the 'standardised care' that had been produced - with the whole or an extract from the protocol, guideline or

pathway being included in twelve papers – none described the process of interpreting the evidence or decision making.

Documentation: The standardised care took a variety of forms. Five studies reported developing a flow diagram or a flow chart with a proforma for nursing assessment or an algorithm, as an easy-to-follow format and user friendly tool.

Other forms of documentation included a protocol of care development with management suggestions on the reverse; a form to notify primary healthcare team members of an expected death; a protocol for prescribing which clarified responsibilities and gave instructions for nursing/medical review.

In two studies, the existing documentation was modified, for example adding guidelines to existing patient information or amending documentation for the Liverpool care pathway.

Approval: Nearly a third (10/33) gave details about obtaining formal approval for the standardised care either from Trust-wide committees or the working group responsible for developing the protocols. As predicted in the Guidance (MA/NICE 2002), each organisation had its own system of delegated authority. This was shown by the range of committees that sanctioned the use of the standardised care. These included the local Medical Ethics Committee, the audit department, the Drugs and Therapeutics Committee and the Clinical Board.

STEP 9 PILOT THE PROTOCOL	**Main activities** • Train and support the users of the protocol • Pilot the protocol • Evaluate ease of use, the effectiveness and impact on staff and patients • Obtain corporate 'sign off'

This step is the start of implementation. Most studies (23/33) reported training users, seven described piloting the protocol, 11 reported some form of audit or pre/post evaluation and 10 obtained corporate level 'sign off.'

Training: A variety of training initiatives were described in 23 studies. Some studies outlined the content or format of the educational programme, who it was delivered by and the recipients. The training was targeted at nurses, midwives or health visitors in 11 studies or members of the multi-disciplinary team in seven studies. A range of formal and informal, group and individual training sessions with practical demonstrations in clinical situations were described. The content focused on the skills and knowledge needed for the new task or role covered by the standardised care. In two studies, the training was provided jointly by hospital and university staff, or by members of the working party and by clinical nurse specialists.

Piloting: Seven studies reported on some form of piloting, with three studies specifying the length of the piloting process (between three and six months). Two studies were reporting just on the pilot phase, with a small number of patients (12 over six months and 52 over 12 months respectively). One study stated that no pilot was undertaken.

Assessment: An additional step was mentioned in five studies. This was a formal or informal assessment of competence, four of which were conducted by medical practitioners.

Evaluation: Some form of evaluation or audit was mentioned in a third (11/33) of the studies. Developing an audit tool, criteria, documentation or an audit strategy was noted in four studies, three of which reported the findings. Four studies described audits at the start of nurse prescribing or drug administration as a safety check.

STEP 10 IMPLEMENT THE PROTOCOL	**Main activities** • Include in Service Level Agreements with commissioners • Train users and provide back-up support for problems • Identify team member to be made responsible for maintaining the protocol

A number of implementation experiences and activities were reported. Three studies referred to their experience of implementing change. These included using change management strategies, barriers to change and the difficulties of change.

Dissemination: Different aspects of dissemination to support implementation were noted, including disseminating the audit results or the guideline to raise awareness of the standardised care or identifying key members of staff to promote the guideline Sustainability: None of the studies mentioned including the standardised care in Service Level Agreements or nominating a member of development team as responsible for the longer-term maintenance.

STEP 11 MONITOR VARIATION	**Main activities** • Document and monitor variations • Review the protocol as a whole

Compliance: Six studies made some direct or indirect comment about compliance with the standardised care. Variations were found in two studies that retrospectively audited case notes over six to seven months after the implementation of standardised care. One study revealing that 42 per cent did not comply with the protocol. Both these studies describe redesigning the content and layout of the protocols to make them easier to use.

Outcomes: Many studies (20/33) provided some audit data as a way of indicating compliance and the impact of the standardised care, especially on patient outcomes and waiting times. Only five studies gave any detail about the impact of standardised care on staff. These impacts included a reduction in time spent by community nurses with patients and two audits demonstrating changes in practice.

STEP 12 REVIEW THE PROTOCOL	**Main activities** • Keep the protocol under review to keep it up-to-date and measure benefits • Train new staff • Use the findings to inform organisation-wide and national agendas

Many studies (19/33) said that the standardised care was being, had been or should be reviewed. Seven studies recommended that the standardised care should be monitored and updated regularly. A variety of review mechanisms were described including annual clinical audit and retrospective audits, staff questionnaires, patient outcomes and satisfaction, and the cost implications

Some studies illustrated how the standardised care had been revised, developed or extended to other parts of the organisation, suggesting that the 'standardised care' was being sustained.

4.1.3 Summary of evidence from the literature

Within the included studies there was very little acknowledgement of the role or job type of the staff responsible for different aspects of standardised care development and implementation. Given that these papers are drawn from nursing journals, state the involvement of nurses, midwives and health visitors in the development of standardised care and have a focus on sharing practice, they are understood by the review team to largely reflect nursing activity, however this is not specified in most cases.

The guidance framework used here to analyse activity outlines an optional, 12-step process for the development and implementation of standardised care. From the sample of papers analysed here it is clear that local protocols were seldom developed in such a linear fashion or with all 12 steps being completed.

All 33 studies reported the process for selecting and prioritising a topic. Other activities that nurses, midwives and health visitors were likely to report were identifying secondary purposes, producing the standardised care document, providing training and getting involved in implementation.

Areas of development and implementation which figured much less frequently than the activities reported on included setting up regular meetings (e.g. a steering group), involving patients and users, reviewing literature, piloting the standardised care, dissemination of the standardised care and checking compliance.

Although many of the stages covered by the framework are common to each account, there was wide variation regarding the sequencing of the process. For example gaining the support of key stakeholders was not confined to step 5. It seemed to require on-going negotiation to gain approval for changes in the working practices, particularly from medical consultants when the change involved expanding the scope of nursing practice and doctor-nurse substitution. That means it is difficult to understand from this literature, what the day to day realities for staff involved in development and implementation. It also suggests that the contribution of nurses, midwives and health visitors is more complex than as presented in the 12 steps guidance (MA/NICE 2002).

There were some notable gaps in the activities and roles described in the literature that was reviewed. For example, the process of interpreting the research literature or the decision making involved in producing standardised care fit for the local context was not mentioned in the Guidance or any of the 33 papers. The leadership role was not referred to in the Guidance (other than the clinical lead or protocol co-ordinator), and was only reported in a single paper.

These findings, whilst illustrative of the types of activities undertaken, also indicate the lack of evidence around both the (often complex) process of development and implementation and the specific contributions of nurses, midwives and health visitors to standardised care.

4.2 Involvement of nurses, midwives & health visitors

Although evidence from the systematic literature review was assumed to relate to the activities of nurses, midwives and health visitors, their involvement in the development of standardised care was understated in the literature. In this section, data from the national survey is used to confirm their involvement. The survey findings demonstrated that nurses, midwives and health visitors contribute extensively throughout the whole process: from development, introduction, use, updating and audit of standardised care. Table 4.1 gives further details.

Table 4.1. Involvement in the different stages of standardised care.

	Not at all/ a little	Moderate extent	Great extent
Led development of standardised care	57.1.%	23.1%	19.8%
Developed standardised care	50.2%	25.4%	24.4%
Introduced standardised care	44.7%	26.8%	28.5%
Used standardised care	9.5%	24.6%	65.9%
Updated standardised care	45.9%	23.8%	30.3%
Audited impact of standardised care	59.6%	19.5%	20.9%

N = 2,596-2,610 depending on missing values

Nearly two fifths of respondents to the survey (42 per cent) reported leading the development of standardised care to a great or a moderate extent; almost half (49 per cent) had contributed to the development of standardised care and 55 per cent had been involved in introducing standardised care. These findings show how prominently nurses, midwives and health visitors are involved at the development stage. The results may reflect the age and experience of the respondents (see appendix 3a for details), although this population mirrors that of registrants with the Nursing and Midwifery Council (NMC, 2007).

The survey findings confirmed the perceptions of the opinion leaders and the experiences of case study participants that nurses, midwives and health visitors are central to the

development and implementation of standardised care. One of the opinion leaders, a practice development nurse, suggested that nurses had championed care pathways in the United Kingdom, saying that …

> 'Care pathways have been driven by the nursing hierarchy in the UK, being nursing focused, and it is usually a nurse that is the champion of developing a care pathway.'

In addition, table 4.1 shows the involvement of nurses, midwives and health visitors in the use, updating and audit of standardised care. Over 90 per cent reported using standardised care to a great or moderate extent; 54 per cent had been involved in updating standardised care; and two in five had audited the impact of standardised care. These findings confirm that nurses, midwives and health visitors are considerably involved in all stages of the development and implementation process.

4.3 Roles in the development of standardised care

The opinion leader interviews and case studies gave an insight into the multiple roles played by nurses, midwives and health visitors at the development stage. Both methods provided examples of these staff groups instigating, leading, co-ordinating and contributing directly and indirectly to the development of standardised care.

The 35 opinion leaders were asked whether and how nurses, midwives and health visitors contribute to the development of standardised care. Most confirmed their involvement, with half portraying development as a multi-disciplinary activity. Nurses, midwives and health visitors were said to play a variety of roles at the development stage. These roles are discussed in turn.

4.3.1 Leadership

Eight opinion leaders gave examples where members of the nursing and midwifery community had started or led the development of standardised care. First hand examples of a midwife, nurse and a health visitor instigating standardised care were given by a medical consultant, a nurse and a health visitor. Each had taken the lead role, seeing the guideline or care pathway through to implementation. A medical consultant described it as …

> 'A midwife who has seen there is a major issue with substance misuse in young mothers, had analysed why there is a major problem and has developed ways of providing a service which is fantastic for these mothers. Developing guidelines and protocols which are appropriate, which save a lot of anxiety, and to my mind, work extremely well'.

All the case studies confirmed the leadership role of nurses, midwives and health visitors in the development, implementation and audit of standardised care. Five of the six case studies were led by these staff groups. The only exception was the myocardial infarction care pathway which was instigated by a medical consultant. The development team for this pathway included a staff nurse from the coronary care unit, who became the pathway co-ordinator. She described herself in the following terms …

'I was fairly junior at that time but I had looked at care pathways as part of my dissertation for my degree so that's why I was involved. I had a little bit of knowledge.'

The case studies show the variety of ways that standardised care can be developed (see appendix 4c for details of each case study).

4.3.2 Continuity of leadership

One of the most striking points across all the case studies was the importance of continuity of involvement of the instigators. The key staff, the operational leads, retained responsibility, either continuously or intermittently, for the standardised care they initiated. This sometimes stretched from the late 1990s or early 2000s to the present day, for example in one case study the health visitor lead was on a part-time secondment for five years.

In two other case study examples the leader's role had been more intermittent. In both cases, staff left after the launch of the standardised care, then returned two-three years later in a management post with a remit for the quality of services. In both instances the lead commented that in their absence, the standardised care was …

'less visible, it was not being driven'…

… and not used consistently, but that they were now in a position …

'to direct and make things happen.'

These examples of continuity of leaders and champions show that the development stage is just the start, and that ongoing commitment is important for maintaining and sustaining the standardised care. Such continuity is perhaps one of the unique contributions of nurses, midwives and health visitors to standardised care.

4.3.3 Resourcing of leaders

In two case study sites, development of standardised care was undertaken by existing staff in addition to their normal work and in the other three, the responsibilities were associated with a specific post. In a final example the funding was mixed.

In the midwifery case study, a part-time midwife was originally appointed on a short-term contract to develop midwifery-led care guidelines. External funding to employ a care pathway co-ordinator was obtained for both nursing case studies, although in different ways. The nurse manager of a palliative care team and the lead cancer nurse gained approval to introduce the Liverpool end of life care pathway into a district general hospital and then secured funding to employ a full-time nurse to roll-out the pathway. In the other nursing case study, Health Action Zone funding was used to fund a full-time care pathway co-ordinator.

With regard to the MI pathway, the consultant lead described…

'managing to nail a drug company'

… for short-term, part-time funding for the staff nurse leading the process, to continue to manage and maintain the myocardial infarction care pathway.

What these findings suggest is that although leadership and continuity of leadership appear critical to the successful implementation and maintenance of standardised care, the resources for doing this work are often provided on an 'over and above' usual duties basis, or are funded via a variety of not necessarily very secure sources.

The costs associated with development are discussed in more depth in chapter 7.

4.3.4 Direct involvement of end-users

Some nurses, midwives and health visitors were also directly involved in development as members of the uni-disciplinary or multi-disciplinary working party or authoring team responsible for producing the standardised care. Direct involvement was a feature of all the case studies, with experienced and interested staff contributing to the development of the guidelines, protocol or pathways. Membership of the uni or multi-disciplinary development group seemed to be determined by expertise and not just seniority or length of practice experience. For example, a student heath visitor, who had been a community psychiatric nurse was a member of the working group that developed a maternal mental health protocol.

Interestingly, there was some disagreement amongst the opinion leaders about the direct contributions of front-line staff as end-users of the standardised care. The involvement of the staff expected to use the standardised care was emphasized by nine opinion leaders. A nurse in policy making role commented …

> *'I do feel that the first principal of, the people who are going to use it need to be involved, it is really important.'*

This was for a number of reasons including resourcing issues …

> *'Division of labour, with people identifying the evidence, working up the protocol and taking it through the speciality.' (clinical governance lead)*

To enhance ownership of the final product and smooth the acceptance of change …

> *'to get buy in at an early stage' (health visitor)*

> *'If they do not feel represented, in the development then they are not going to own it and they are not going to use it.' (nurse manager)*

> *'I think it is important to get everybody involved because then the actual implementation and the change is accepted, and it is far easier.' (nurse practitioner/researcher)*

Improving skills and practice, or making sure that everyone was clear on the contents of the standardised care was also cited by a number of opinion leaders and case study interviewees …

> *'almost as a learning tool as much as anything … learning and improving practice' (nurse in policy making role).*

However, a few opinion leaders expressed reservations about the feasibility of involving end users. These were in the main due to resourcing issues. For example, a nurse in a policy making role, highlighted the tension between involving a variety of staff and the practical problems of time and competing demands …

> 'In an ideal world, it would be a good mix of clinical nurses and someone from the university and someone from practice development and multi disciplinary. That would be the ideal achievement, but I know when you try to do that, it adds another two years to the projects. You can never get everyone together, the clinical nurses can't get released.'

A practice development nurse added a quality control rider …

> 'just to let practitioners necessarily to go off under their own steam, it doesn't bring in the sort of quality control and governance checks.'

This concern about quality was not mentioned or apparent at the case studies where the development teams also comprised experienced staff, the process had included a review of research and relevant policy to ensure that the standardised care was evidence-based, and the documents were scrutinised and endorsed by the trust.

4.3.5 Indirect involvement of end-users

The opportunity to contribute indirectly through formal or informal consultation mechanisms was highlighted by opinion leaders and evident at the case study sites. Such indirect involvement in the development stage was said to be important for adoption of the standardised care, to secure 'buy in' acceptance of the change in practice, and ownership by front-line practitioners. A nurse, in a policy making role described her previous experience of using meetings with all charge nurses and ward managers to consult about drafts asking questions such as:

> "What do you think of it? Do you think this is workable?"

Extensive consultation and communication with front-line staff was described at the midwifery case study and one of the health visitor case studies. Such direct and indirect contributions supported adoption and also understanding and pride in the standardised care. For example, the operational lead for the midwifery-led care guidelines started by asking midwives about what they …

> "didn't like doing and developing a list of the ten aspects of practice that were most important to change, and then reviewed the research about these interventions.

Drop-in sessions were used to …

> 'get lots of discussion about the guidelines'

… and feedback was sought as the drafts were distributed to all midwives. All the midwives spoke positively about the midwifery-led care guidelines.

Two methods of gaining contributions from front-line staff were reported at a health visitor case study site. Firstly, the pathway was developed by a strategic and a core group with former overseeing the process and the core group working on specific tasks

such as the training needs analysis. The operational lead was said to vary membership of the task group, to involve staff with expertise on the topic, so that all staff had the opportunity to contribute. Secondly, all health visitors were indirectly involved, receiving regular up-dates at the monthly forum meetings. This way of communicating with all staff, by cascading progress reports, asking for and responding to feedback was valued by informants. For example, a health visitor described providing extra training following a request from nursery nurses at their forum. Consultation was important to explore the usability of the pathway, to find out what would work in practice.

Indirect involvement or 'representative' participation (e.g. Cotton, Vollrath, Froggatt, Lengnick-Hall and Jennings, 1988) ensures that nurses', midwives' and health visitors' views are still sought by those engaging in decision-making regarding standardised care. The more general point is that direct or indirect participation in the development, and also the ongoing improvement of standardised care, gives end-users more control and a 'voice' regarding decisions that affect their working practices. Such involvement also facilitates psychological 'buy-in' or ownership of standardised care and ensures that procedures are practically viable and useable.

4.3.6 Brokerage role

Acting as a broker was mentioned by one of the opinion leaders and the importance of this role was evident in several of the case studies.

A nurse in a joint academic/practice post, described how nurses may act as brokers between medical practitioners, negotiating differences of opinions between consultants about what is the right practice. She described this as …

> *'one of the biggest tensions'*

… when developing and implementing protocols, especially when there is …

> *'resistance from medical staff.'*

The brokerage role appears to be a specific component of the leadership activities described by staff in 4.3.1 where one or more people are responsible for supporting and negotiating the continued use of the standardised care across different groups, and over time.

4.4 Factors facilitating involvement

In this section the factors that influence the participation of nurses, midwives and health visitors in standardised care are presented. Two professional 'pull factors', namely expertise and improving patient care, were found to be particularly important for the adoption of innovations and part of the unique contribution of these staff groups.

Such 'pull' factors (Leseure *et al* 2004) can be important where standardised care is developed as a bottom-up response to a local need, rather than being 'pushed' down, or imposed from the centre.

A third factor, extending the scope of nursing practice was a pull factor both in professional terms and as a result of organisational priorities. A fourth factor was the specific work role of the nurse, midwife or health visitor, which was predominantly determined by the organisation.

4.4.1 Area of expertise

There were many examples of specific expertise prompting the development of standardised care in both the opinion leader interviews and the case studies. It was noted by one opinion leader, a medical practitioner, as pertinent to the work of nurses, midwives or health visitors …

> 'an extension of their area of expertise … so for example, discharge guidelines – all the things that need to be done before a child is discharged would be very much nurse-led.'

The midwifery-led care guidelines at the midwifery case study were the strongest expression of a *'pull'* factor. These were instigated by a Head of Midwifery in what was described as part of *'gutsy management drive to introduce midwifery-led care with confidence'* in the late 1990s. The evidence-based guidelines allowed this to happen, to get this going in a safe way. Midwifery-led care refers to maternity care given solely by midwives to low risk women. It empowers midwives to resist social pressure to conform to the medical model of care (Walton, Yiannousiz & Gatsby 2005). It provides an alternative to obstetric-led care for low risk women that is congruent with midwifery values about childbearing as a normal physiological process and an event of significant psychosocial importance (Spiby & Munro 2001). Midwifery-led care is described as allowing midwives to reclaim their role by asserting their expertise in normality. Therefore, professional values facilitate or motivate their involvement in this area.

4.4.2 Improving patient care

Improving patient care was the major motivating force for nurses, midwives and health visitors. This 'pull' factor was evident in the literature review, emphasised by the opinion leaders and apparent at the case study sites.

Developing standardised care was a proactive response to a local problem or need was the most frequently mentioned reason in the development/implementation systematic literature. Standardised care was a bottom-up, local innovation in response to a specific need in 28 of the 33 UK papers. This is exemplified by Ayris (2002) who wrote as follows…

> 'Following on from a particularly long delay of 8 hours in the verification of one patient's death by the out-of-hours deputising service in our area, I decided that it would be helpful to … develop a protocol for use in the Trust' (p371).

An opinion leader, a nurse manager, expressed a similar motivation, when reflecting about the management of constipation, a topic which overlaps with area of expertise. She commented …

'I was looking at the fundamental care we give the residents. One of the common complaints is … "I'm constipated, nurse, or matron or whoever" … I looked at how we manage constipation and I just felt that we weren't doing it very well … We're still very led by the doctors… from what I read in the literature I just thought that … there is a better way and perhaps a protocol might be the answer.'

Four operational leads at the case study sites used the word 'passion' to convey their motivation for developing standardised care to improve patient care. Their passion was multifaceted, encompassing an in-depth interest in the topic and knowledge of the latest research such as the importance of bonding and attachment for long-term well being, as well as a vision of transforming professional services by offering women midwifery-led care or public health interventions by health visitors.

4.4.3 Safely extending scope of practice

Almost a third (10/33) of the studies in the development/implementation review portrayed standardised care as a means of facilitating a nurse-led service or expanding the scope of nursing practice in a safe way. As such, standardised care provided a relative advantage that supported adoption (Greenhalgh *et al* 2004). Some were instigated by a nurse's desire to improve patient care, such as the example of district nurses verifying expected deaths quoted above (Ayris 2002). Other examples involved service reconfigurations, with nurses acting as the first point of contact as an organisational response to national targets or the reduced availability of junior doctors. For example, Dibb, Fawcett and Whall (1999) said that the main impetus for a pre-operative optimisation protocol was financial, to employ senior nurses rather than doctors. They observed that …

'The role of the nurse in the intensive care environment is ideally suited to taking full advantage of the use of protocols. This is due both to the close working relationship with members of the multi disciplinary team, and also to the occasional blurring of boundaries between medical and nursing responsibilities. This has the potential to make it easier for nurses to take on additional practices with little effect on their perceived levels of responsibility or expansion of their roles' (p15).

The organisational responses to national priorities such as reducing waiting times and workforce reconfiguration could also be categorised as top-down or institutional push factors to stimulate the adoption of standardised care.

Extending scope of practice was mentioned as a pull factor and a concern by some opinion leaders. For example, a nurse specialist who had developed a guideline for nurse-led discharge, that was scrutinised and approved by the Trust Clinical Risk Committee, spoke about her concerns regarding her professional registration, saying …

'I was stepping outside the boundaries of nursing. It was a much more contentious protocol … it took a time because of going through Clinical Risk, but I knew I had to do that … being covered. I don't want to take on a role that might jeopardise my registration.'

This point about safe practice was noted as a key reason for accepting standardised care by four opinion leaders. A nurse with direct experience expressed this as …

> *'I think they are almost like a security blanket, in a way, because you've got something telling you what you should do.'*

The connection between safety, nurse education and registration with the Nursing and Midwifery Council (NMC) was made by a nurse researcher in a joint practice/academic post who observed …

> *'Nurses … if they are doing a procedure, obviously they have to practice under supervision, they will have to do a theory test behind it, they will have to do a practice, they will be signed off as competent to do it. So their training is completely different from doctors. That is why I think they are so suited to work within a protocol. The protocol really, it empowers them to be autonomous, but with a safety net for their own practice, and for their own professional registration number in many respects.'*

The formal or informal assessment of competence was an unexpected and additional step that emerged in the development/implementation literature review. Such an assessment was reported in five of the 33 UK studies, four of which were conducted by medical practitioners. For example, Birchall *et al* (2002) note that two nurses completed a competency-based assessment after the first six months and Porrett *et al* (2003) report that the nurse practitioners saw patients independently having been assessed as competent by the consultant.

4.4.4 Leadership and management roles

The fourth pull mechanism had an organisational as well as a professional element, in that contributing to the development of standardised care was intrinsic to the work role of nurse consultants, strategic managers and practice development staff. Examples of such roles were given by opinion leaders and were evident the case studies. An opinion leader, a health visitor manager noted that …

> *'Myself and a lead nurse for district nursing, have a strategic overview for these services and we work with development nurses, Health Visitors, District Nurses, School Nurses and Sexual Health Nurses, to develop the standards and the guidelines within the clinical practice resource services.'*

A practice development midwife summarised her remit as 'purely around evidence-based practice, audit and continuing professional development' saying that she had been supporting guideline development since the late 1990s, and a practice development nurse described how she wrote multi-disciplinary pain management guidelines with anaesthetists, consultants and nurses.

4.5 Barriers to involvement

A number of issues were raised in relation to the difficulties faced by nurses, midwives and health visitors which could impact on their ability to contribute to the development and implementation of standardised care. Whereas the factors that promote involvement are to do with professional role, skill development and patient care, barriers exist mainly in the form of day to day pressures on staff, namely time resources, financial resources and staff shortages.

4.5.1 Time

The time demands involved in developing standardised care were mentioned by eight opinion leaders. These were reported as the amount of time required to review evidence …

> *'read and absorb … You cannot just read them and leave them in the folder. You need to make sense of them and use them.'*

Lack of time was also exacerbated by workload and staff shortages, as a midwife in a policy influencing role observed …

> *'they are so busy, especially at the moment whilst there is a shortage of midwives, to be able to think about protocols.'*

Conflicts with other demands were mentioned, particularly where development and implementation work was carried out in addition to a normal case load. A member of the protocol development group at one case study site acknowledged the extra time required …

> *'to pull three protocols together'*

as this was done on top of her case load. She explained that as a health visitor, she was measured on the number of client contacts. This meant that…

> *'attending a three hour meeting was expensive because she could have seen three families.'*

Yet she stressed the importance of directly involving end-users, to understand …

> *'what would work in practice … otherwise the protocol wouldn't take off. I wouldn't like it to land on my desk as a fait accompli.'*

4.5.2 Financial resources

> The economic analysis at three case studies estimated the resource use, particularly the time costs involved in developing, implementing and monitoring standardised care (see chapter 7 and appendix 6). Although the findings are ''best estimates', based on documentary evidence and the recall of the operational lead, the figures are substantial and reveal the hidden cost which is primarily borne by nursing, midwifery and health visiting budgets. Staff shortages

Staff shortages were mentioned by six opinion leaders, with a midwife with a direct experience, illustrating the link between staff shortages and the need to give priority to patient care, saying the …

'*sheer shortage of midwives … they get plucked back at the last minute because we have not got the cover on labour ward.*'

4.6 Summary

The literature review identified a wide range of tasks and activities involved in the development and implementation of standardised care, however the involvement of nurses, midwives and health visitors was largely understated.

What was evident from the literature review was that the process is rarely linear and that development and implementation activities vary considerably across studies.

The survey and opinion leader interviews confirmed the central role of nurses, midwives and health visitors in all aspects of development and implementation. Their leadership role was particularly highlighted and the importance of continuity of leadership for maintaining impetus. However, this important role is often done on an 'above and beyond normal duties' basis, or where funding is secured it is often from additional or one-off sources.

Both direct and indirect involvement of end users of the standardised care was seen as important for a number of reasons, mostly to get 'buy in' or ownership of the standardised care, but also to improve skills. However the difficulty of including all staff in such consultation phases (largely due to resource issues) was noted.

The importance of a final, central role for nurses, midwives and health visitors was highlighted – that of a 'broker', negotiating consensus around best care and use of the standardised care both across professional groups and over time.

The driving factors influencing involvement in the development and implementation of standardised care were identified in four main categories: specific expertise in an area; desire to improve patient care through observation of practice and what could be done better; extending the nursing role and specific organisational roles (e.g. for practice development).

The factors driving involvement in the development and implementation of standardised care and the roles undertaken by nurses, midwives and health visitors were found to be consistent regardless of the variant of standardised care in question (eg guideline, care pathway, protocol etc).

Some of the facilitators and barriers to implementation and adoption of standardised care approaches are discussed in the next chapter.

5 Positive and negative impacts on staff

The final aim for this research was to assess the overall impact of the introduction of standardised care upon the work of nurses, midwives and health visitors, including their sense of professional identity and capacity. The different of types of standardised care, variations in how they are understood and applied in practice, and the variety of roles that nurses, midwives and health visitors play in their development and implementation all point to a wide range of possible effects and outcomes.

Although standardised care is generally seen as having clear benefits for patient care, this report has highlighted that there is some conflict between the view that standardised care benefits patients and the perception that this approach may result in less individualised care, and fails to acknowledge sufficiently the role of uncertainty and the importance of clinical discretion. Similarly, the literature discussing the impact of standardised care on health professionals' experiences of work abound with conflicting opinions, and much of this arises from the inherent tension between standardised care's emphasis on controlling and guiding employees' behaviour to reduce error and increase safety versus allowing professionals to use clinical judgement in the provision of care. Critics argue that care delivery from front line practitioners has become heavily bureaucratised, with professionals' performance increasingly governed by rules and procedures (Harrison & Smith, 2004), accompanied by deleterious effects on innovation, trust and morale (Berwick, 2003). This negative view of standardised care is consistent with much of the human resource management literature, which advocates a 'commitment' model of employee relations, where co-ordination and control are founded on shared goals and values, encouraging commitment, as opposed to traditional control models based on rules and procedures (Walton, 1985).

This chapter draws on two sources of evidence to explore the possible positive and negative outcomes of standardised care through existing evidence and opinion leader perceptions. The findings are then discussed in light of existing research from other sectors. Chapter 7 tests these theories further through findings on impact from the national survey of nurses, midwives and health visitors.

In chapter 5:

Section 5.1 reports findings from a systematic review of the literature which identified empirical research on the impact of standardised care on nurses, midwives and health visitors and Table 6.1 provides an overview of results with findings presented in eight impact categories.

Section 5.2 presents findings from the opinion leader interviews with regard to their views or direct experience of the impact of different forms of standardised care and provides a much richer insight into the possible positive and negative consequences of standardised care.

Section 5.3 discusses the conflicts emerging from these findings and considers them in the light of evidence from organisational research literature on formalisation.

5.1 Evidence from the literature about impacts

In March 2005 electronic searches were undertaken of five nursing databases using a combination of the search terms 'protocols', 'guidelines' and 'care pathways'. This generated 6,648 potentially relevant titles and abstracts. Titles and abstracts were sifted against inclusion and exclusion criteria developed to identify articles which reported on the impact of a form of standardised care on nurses, midwives or health visitors. To be included in the review, studies had to meet the following criteria:

- Population: Nurses, midwives or health visitors

- Intervention: any form of standardised care

- Comparitor: non specified

- Outcome: any form of outcome related to the population's experience of work

Additionally, studies had to be evaluative (rather than descriptive) using a clearly stated research method or audit and be longitudinal in nature. (The full methodology for the systematic review is presented in appendix 2a and detailed evidence tables are presented at appendix 2e. The references for this review are given in appendix 2f).

5.1.1 The nature of the evidence base

Of the 6,648 titles and abstracts considered, a total of 95 studies were identified from international research that appeared to report on the impact of a form of standardised care on staff. The full papers of these titles and abstracts were ordered and subjected to in-depth review. Thirty studies subsequently had to be rejected for unclear or irrelevant content and one was a duplicate so was removed from the review. Data from the remaining 64 studies were put forward for data synthesis. Overall, this represents a very small body of evidence with few studies considering the impact of standardised care on staff.

In the majority of studies, the impact of standardised care on staff was not the main focus of the research and it was typical to find relatively little information given in the paper about methods or outcome measures for this part of the research. Outcome measures relating to staff impact ranged from questionnaire surveys through interviews, audits, chart reviews and focus groups to observations. In some cases, the data on impact was no more than anecdotal. Overall the research in this area has focused on patient rather than staff outcomes. As a result, the body of evidence for this review is based on a small number of scientifically weak papers and represents a lack of robust evidence about the impact of standardised care on nurses, midwives and health visitors. A range of limitations was identified within the studies including:

- no information on sample size, or where it was given, often the samples consisted of highly motivated staff who had volunteered for additional duties in relation to the standardised care;

- little (or in some cases no) information on how the impact of standardised care on staff was measured;

- where information was given there was little use of validated outcome measures;

- little attempt to control for bias;

- few studies presenting actual data – the impact on nurses, midwives and health visitors often being reported anecdotally; and

- most studies characterised by being highly context specific.

Although there were exceptions to this pattern, the body of evidence overall is weak and the extent to which the findings can be generalised is limited.

5.1.2 Findings on impact

The studies covered a wide range of outcomes. These were content analysed and grouped into eight impact categories (see Table 5.1). Fifty eight of the studies identified reported positive findings for the impact of standardised care on nurses, midwives and health visitors, six studies reported negative findings.

Findings in each impact category are summarised in turn. Details of studies can be found in appendices 2e and 2f.

5.1.3 Team working

Twenty one studies reported on the impact of standardised care on team working, only one of which stated that improved team working was an aim of introducing the standardised care. All twenty-one studies identified improved team working as a positive impact of standardised care on nurses and health visitors (no studies were found in relation to midwives). Moreover, many of the studies reported multiple impacts, such as expanded nursing roles and increased satisfaction, so although not the most robust data, the picture that emerges is consistent.

5.1.4 Expanded nursing role

The nursing literature refers to both expanded and extended roles for nurses. This definition views role expansion and role extension as distinct concepts, with 'expansion' concerned with increased skills and knowledge, and 'extension' concerned with the performance of tasks usually considered to be outside the confines of nursing, as described by Frost (1998). However, both terms are used interchangeably in the literature, with a more general meaning encompassing both enhanced nursing skills and

Table 5.1. Impact outcomes measured in the research

Impact Category	Impacts on Nursing Staff
Team working	Improved team working
	Improved communication
	Increased collaboration
	Increased awareness of roles of others
Expanded nursing roles	Expanded nursing role/responsibility
	Increased proactivity
Clinical freedom	Increased autonomy
	Empowerment
	Constrained use of own knowledge/experience
Job satisfaction	Increased satisfaction
	Increased confidence
	Increased commitment
	Improved morale
	More positive attitudes
Stress	Reduced stress
	Increased role clarity
	Reduced role conflict
	Reduced role overload
Patient care and understanding	Better understanding of patients
	Better communication with patients
	Increased motivation to care for patients
	Reduced quality of nursing as more protocols available
Clinical knowledge	Increased clinical knowledge
	More informed about overall care process
Clinical skills	Increased skills & abilities
	Restricted decision making
	Deskilled nursing role

an enlarged nursing practice. For the purposes of this review, the term 'expanded role' has been used to represent both the expansion and extension concepts.

Twenty studies reported on the impact of standardised care on the expanded nursing role. All of these concerned the impact on nurses; no studies were found in relation to the impact on health visitors or midwives. All 20 studies found standardised care to have

a positive impact in expanding nursing roles to include procedures and treatments considered as beyond the usual scope of nursing practice.

Seventeen studies also identified a number of other impacts on nurses as a result of standardised care. These included improved team working, increased clinical knowledge, increased clinical freedom, increased job satisfaction (including improved confidence and increased commitment), increased clinical skills, improved patient care and understanding, and reduced levels of stress.

5.1.5 Clinical Freedom

Clinical freedom in this review is understood in terms of the levels of autonomy and empowerment given to and experienced by nurses, midwives and health visitors. The studies in this section are all concerned with the freedom to make clinical decisions.

Fourteen studies examined changes in levels of autonomy and empowerment as an impact of standardised care. All of the studies were concerned with the impact on nurses, as opposed to the impact on health visitors or midwives.

All but one of the studies included in this clinical freedom dimension considered standardised care to have a positive impact on nursing staff. Nurses working with standardised care were reported to have increased clinical freedom, as a result of increased autonomy and empowerment. One study reported standardised care to have a negative impact on nursing staff because the use of their own knowledge and experience is constrained.

All of the studies identified other impacts of standardised care, including: improved team working; expanded nursing roles; job satisfaction (including improved confidence and increased commitment); increased clinical knowledge; improved patient care and understanding; reduced levels of stress; and increased clinical skills.

5.1.6 Job satisfaction

Job satisfaction is one of the most widely studied variables both in the work design and health care literatures (Patterson *et al*, in press). Nearly half the studies (30/64) in this review report on some form of job satisfaction measure. In addition, studies which reported impacts on confidence, commitment, morale and attitudes, (i.e. factors associated with satisfaction) were included in this job satisfaction dimension.

Twenty-eight of these studies considered the impact on nurses and the other two concerned the impact on midwives; the impact on health visitors was not investigated. The impact of standardised care on nurses and midwives job satisfaction was the primary focus of twenty-two studies. However, none of the studies reported on standardised care aimed at improving job satisfaction.

All 30 studies considered standardised care to have a positive impact on nurses and midwives, resulting in increased levels of job satisfaction, including increased confidence, commitment and morale, and more positive attitudes.

Twenty eight studies identified multiple impacts of standardised care in addition to increased job satisfaction. These included 13 studies reporting improved patient care and understanding, 12 increased staff knowledge, 11 mentioned improved team working, 11 reported increased clinical freedom as a result of increased autonomy and empowerment,

10 included increased staff skills, seven reported expanded nursing roles, and four reported reduced levels of stress.

5.1.7 Psychological well-being (stress)

Four studies examined the impact of standardised care on the stress levels of nursing staff, none of the studies concerned the impact on midwives or health visitors. In addition to specific mentions of stress, studies which reported impacts on nurses' role clarity, role conflict and role overload were included in this review, as these three factors all affect psychological health.

The impact of standardised care on nurses was the primary focus of each of the four studies, however, none of the studies report on standardised care with the specific aim of reducing stress or improving psychological health.

All four studies found that working within standardised care had a positive impact, reducing the amount of stress experienced by nursing staff due to increased role clarity, reduced role conflict and reduced role overload.

In addition to reduced stress levels, many other impacts on nurses were also identified by these studies. All four studies reported increased job satisfaction, three studies reported increased clinical freedom (increased autonomy and empowerment), two included improved team working, two included expanded nursing roles, one study mentioned improved patient care and understanding, and one study mentioned increased staff knowledge.

5.1.8 Patient care and understanding

Twenty-four studies looked at whether standardised care has an impact on the level of care and understanding nurses, midwives and health visitors felt able to give to their patients. Twenty-one of these studies concerned the impact on nurses, two studies examined the impact on midwives and one study looked at the impact on public health nurses (the USA equivalent of UK health visitors). Seventeen studies reported on a standardised care with the direct aim of improving patient care

Twenty three studies reported working with standardised care to have a positive impact on patient care, as a result of nurses having an increased understanding of their patients, better communication with their patients, and an increased motivation to care for their patients.

One study reported that the quality of nursing decreased as more standardised care became available.

The remaining studies identified multiple positive impacts of working with standardised care on nurses. Thirteen of the twenty-four studies also reported increased nursing

satisfaction, nine studies reported increased clinical knowledge, eight mentioned improved team working as a result of following standardised care, seven studies included increased staff skills, five studies mentioned expanded nursing roles, four studies mentioned increased nursing freedom, and one study reported reduced levels of stress. One study, in addition to improved patient care and understanding, reported standardised care to have negative impact on nursing staff, namely that working with standardised care constrained the use of nurses' own knowledge and experience.

5.1.9 Clinical knowledge

In addition to specific mentions of clinical knowledge, studies which reported standardised care to have an impact on the degree to which nursing staff were informed about the overall care process, akin to clinical knowledge, were included in this section.

Twenty-three studies considered standardised care to have an impact on the clinical knowledge of nursing staff. Twenty-one studies focused on nurses, one on midwives, and one on public health nurses (the USA equivalent of UK health visitors). The impact of standardised care on nurses and midwives was the primary focus of twelve studies.

None of the studies reported on standardised care with the specific aim of improving nursing knowledge. Each of the studies included in this clinical knowledge dimension considered standardised care to have a positive impact on nurses and midwives with staff reporting increased levels of clinical knowledge and being more informed about the overall care process.

Twelve studies also reported increased nursing satisfaction as a result of following standardised care, ten studies included increased staff skills, nine mentioned improved team working, nine reported improved patient care and understanding, eight studies mentioned expanded nursing roles, seven studies mentioned increased nursing freedom, and one study reported reduced levels of stress.

5.1.10   Clinical skills

Nineteen studies examined the impact of standardised care on clinical skills and abilities. Eighteen focused on nursing staff, one study looked at midwives. The impact of standardised care on clinical skills was the primary focus of thirteen studies, however only in one instance was the standardised care aimed specifically at increasing nurses' clinical skills.

All nineteen studies identified a positive impact of working with standardised care, resulting in increased levels of clinical skills and abilities for nursing staff. Only one study reported increased nursing skills as a single impact of standardised care on nurses and midwives. The remaining eighteen studies identified multiple impacts of working with standardised care. Ten studies reported increased satisfaction, ten studies found increased clinical knowledge, seven reported improved patient care and understanding, six studies mentioned expanded nursing roles, four studies mentioned improved team working, and three studies mentioned increased nursing freedom.

5.1.11   Summary

The studies identified here present a highly positive picture of the impact of standardised care on a wide range of outcomes. In the main, the studies report on numerous linked outcomes (such as job satisfaction and psychological well-being). Although the data reported are not generally robust, they do present a consistent picture of largely positive impacts.

Overall care is needed in interpreting the findings from this review. Only in the minority of cases were the outcomes reported here either an intended outcome of the standardised care, or the main focus of the study. Additionally, much of the data is more anecdotal than empirical (despite the criteria used to include studies) or insufficient detail is given in the study to ascertain how the data has been gathered.

The findings of the literature review help to illustrate the wide range of possible outcomes that could be affected by the introduction of standardised care. They also highlight the lack of robust scientific consideration given to the impact of this type of change on the staff who are responsible for implementing it.

The next section goes on to identify the possible impacts identified by the opinion leader interviews.

5.2 Opinion leader views on the impact of standardised care

This section presents the themes that emerged from the opinion leader interviews regarding the impact of standardised care on staff. As would be expected from this data, the views were more complex, often highlighting both the positive and negative impacts of standardised care, recognising the importance of contextually specific factors.

Opinion leaders discussed several positive and negative outcomes of standardised care for staff with regards to:

- Procedural support and confidence in clinical practice,

- patient care, and

- well-being and morale.

Positive outcomes were typically attributed to the enhanced sense of autonomy and guidance that standardised care provided. On the other hand, negative outcomes were discussed when standardised care was applied rigidly or when it was perceived as 'coercing' clinical practice. Section 5.2.1 summarises the themes under the positive impacts of standardised care and section 5.2.2 highlights some of the negative impacts described.

5.2.1 Positive impacts

Procedural support and confidence

Opinion leaders discussed several advantages of standardised care for staff including enhanced autonomy, confidence and well-being. The most commonly discussed benefit was that standardised care provided support and evidence-based guidance enabling staff to act proactively and autonomously in providing patient care. Specifically, standardised care was perceived as constituting a 'best practice' approach to treatment often underpinned by research evidence thus enabling staff to feel confident that the approach adopted is the 'right' one. This sentiment was expressed by a practice development nurse …

> *'If the evidence is good, then that would be the advantage that everybody gets that standardised care and you pull people up to good practice who perhaps weren't doing good practice. But also you give people just a bit more confidence in knowing that what they're doing actually does have a good basis behind it rather than, we've always done it this way.'*

In addition to the 'best practice' and evidence underpinning standardised care, another factor perceived as contributing to professional confidence was procedural clarity. Specifically, some opinion leaders observed that standardised care provides clarity regarding how common situations should be approached by describing explicitly all the expected processes of care. This point is illustrated by the comments of a nurse in a policy influencing role …

> *'When we got the Patient Group Directions (PGDs) you had such clarity. If someone's blood pressure was 140/90 you did not give them the combined pill. Up until then, if it was 142/92 you hovered, it was probably OK. You would call them back in 2 months to review the blood pressure for example. Now, you just don't do it. They have to see the doctor, or the doctor will authorise it over the phone. So, it is that clarity which is very important, and very supportive. It gives you a certain amount of confidence, as you work within the PGD. You have made that assessment. You have weighed the patient, taken their blood pressure, written their body mass index, revisited their family history and medications all the sort of things that might affect whether they can have ongoing contraceptives or not so it gives you a great sense of security, I think. I like the cut off points. 40 is it, the clarity is good.'*

This view was also shared was by midwife in a policy making role …

> *'It enables them [midwives] to feel secure that they are doing it the right way, that there is, that it supports their way of working and if there are any challenges, it is easy to say, "well I did it like this because this is the standardised way of doing it" … and they feel boosted by the fact that it's not their personal opinion, but it is written down on the protocol in front of them, saying "if you would like this woman to have a normal birth, the best way to do it is this".'*

Thus, there was a sense that the evidence-based nature as well as procedural clarity of standardised care contributed to professional confidence as well as feelings of security in

one's practice. Furthermore, three opinion leaders recognised that standardised care may be particularly useful in building up the confidence of new and inexperienced staff who may not yet have accrued the knowledge to enable them to be effective in all situations. This point was illustrated by a nurse researcher …

> 'But on the other hand, if you have nurses who are very inexperienced left with a patient then a protocol might be just what is needed. It is probably useful for building up people's confidence in their clinical judgement but once they have that confidence then they (protocols) may not necessarily be needed.'

In contrast, it was suggested that these benefits may be less pronounced for experienced practitioners where '*there's more room for flexibility*' in the use of standardised care as was commented by a health visitor. This view was also expressed by a nurse in a policy making role, as the following quote illustrates …

> "The care can start off being quite protocol driven, but equally once the confidence of the practitioners grow, and indeed I would argue the confidence of the wider team grows …. then you tend to find that it moves away from the kind of prescribed nature of protocols, to more of a kind of "I work within a framework".'

In addition to providing confidence in clinical practice, three informants - two nurses and a policy maker - discussed the positive impact of standardised care on professional confidence in the context of the doctor-nurse relationship. In particular, they commented on how enhanced professional confidence in clinical judgements may also be reflected in 'resistance' or 'voice' in situations where nurses may disagree with doctors' suggestions of possible courses of action regarding the treatment of a patient. For instance, a midwife in a policy making role commented …

> 'If you work with 10 different consultants, they all have a different way of doing it. But one comes into the room, where you're caring for someone, and says, 'why haven't you examined that woman, might want to go ahead and do it'. But no it absolutely doesn't need doing, and saves the woman unnecessary intervention. Yeah. And I think some midwives would have felt bullied into doing it …. they are not saying why haven't you, they are saying, do it. Now, that question, why haven't you, means why haven't you, and the midwife would say, I haven't because it is not required.'

Finally, some informants commented on additional benefits of standardised care in terms of reducing stress. Specifically, six opinion leaders, including three nurses, two medical practitioners and a midwife with a variety of direct and indirect experience, spoke about the positive impact of standardised care on staff well-being. Of these six informants, four had current or past experience as practitioners, whilst the other two had experience researching 'standardised care' and leading developments in a policy making role. For example a nurse with direct experience in a previous post, outlined the impact of standardised care on reducing stress and enhancing a sense of security …

> 'Yes, it gives you permission and something you ought to be doing, it makes it easier and it takes the stress from you and stops you taking problems home with you. It can be very supportive for nurses. To know we are doing the right thing, or we are all doing the same thing … so it gives you a great sense of security, I think.'

In summary, these examples suggest that, because standardised care describes explicitly the processes that should be followed to ensure high standards of patient care, it helps enhance practitioners' professional confidence especially when they are less experienced. Moreover, as standardised care procedures are evidence-based, they may further support clinical practice and reduce stress as they act as a 'security blanket' in cases of potential litigation.

Autonomy in the context of expanding nursing roles

Autonomy was mentioned by 15 opinion leaders, five of whom, all from a nursing background, referred to autonomy in the context of expanding and new roles associated with the modernisation of the NHS. For example, a practice development nurse said …

> *'One of the stated aims in the Modernisation Agency's document on protocols is that government or the NHS want to develop the nurses role, give them more autonomy and so forth and room for growth and protocols is one way of achieving that.'*

New roles were linked with *'practice that has traditionally been delivered by medical staff'* by a health visitor in a policy influencing role and a practice development nurse. Indeed, several opinion leaders (including a nurse manager, a practice development nurse, a medical practitioner and research nurse in a joint practice/academic post) commented that standardised care has enabled nurses to provide care more autonomously. A medical practitioner offered the following opinion …

> *'I think the huge thing that it does for nurses is actually empowering them to give the care that they want to give. And because all the drugs are already prescribed part of the protocol is actually to get the drugs prescribed but having got those there they can then give the care that they want to without really involving the medical staff that much.'*

In some cases, however, standardised care was a way of formalising current practice as was observed by a specialist nurse …

> *'In a sense, I was informally doing it anyway in that the doctors will often leave it to me to decide … that was sort of moving it a step on.'*

In summary, a number of opinion leaders discussed the positive impact of standardised care on autonomy in the context of expanding nursing roles. Within this context, standardised care helped define best practice whilst allowing nurses to carry out tasks that would be traditionally carried out by medical staff. However, several informants also noted that these positive effects may be compromised when standardised care is perceived as constraining rather than enabling clinical practice and when considerate obedience is substituted by blind rule following. The potential negative outcomes of standardised care for staff are discussed in the next section.

5.2.2 Negative impacts

This section deals with the main theme that emerged from the opinion leader interviews which focused on the importance of using standardised care flexibly depending on a patient's needs. That is, while the majority of informants acknowledged the benefits of

standardised care in terms of establishing best practice and supporting staff, there was a general concern that flexibility in practice should be preserved and encouraged.

Preserving flexibility in clinical practice

Fifteen opinion leaders discussed disadvantages of standardised care that related to decision-making and the extent to which it was applied automatically, without thinking or knowledge and without assessing whether it was appropriate for a particular patient. A nurse manager summarised this issue …

> 'Well, I think the drawbacks are - there's a danger sometimes that people follow them slavishly without thinking and so that's why it's really important that people are clear about, if they're following a protocol that they've assessed that they're using the right protocol for the right person rather than making assumptions about ' oh, this must be an X therefore I do Y' … But there is a danger that it stops people thinking.'

The latter point in this quotation was discussed by several opinion leaders who commented on the danger that standardised care may lead to rigidity and prevent staff

from thinking creatively. This drawback may be especially pronounced for new or inexperienced staff who may lack the knowledge to deviate from standardised care when appropriate. The following quote from a practice development nurse captures this concern …

> 'You get a new staff nurse and protocols are fantastic for them. But they can also be a real pain because they can't go off them. They find it really difficult to move outside them as well. So you kind of wonder if in the future it's going to, if they'll be able to do things that aren't on a protocol.'

Similarly, a practice development nurse and a medical practitioner, both with direct experience, expressed concerns about how junior staff or novices gained the knowledge, experience and confidence to move outside the protocol when appropriate, and thus develop their skills and expertise …

> 'If all you do is hand your junior staff the protocol and tell them to get on with it, they will never become experts.'

Indeed, opinion leaders gave several examples where staff had followed standardised care by rote rather than in a reflective manner which was to the detriment of the patient. A midwife in a policy influencing role but with previous direct experience described an instance where guidance had been followed inappropriately …

> 'I've been involved in cases where a midwife has made wrong decisions based on blindly following guidance when it obviously wasn't appropriate. So because I've been involved I know that that has happened. Now, whether that would have happened if the guidance wasn't there in the first place and the wrong decisions would have been made it's hard to know, isn't it? Would the action of that midwife have been appropriate if guidance hadn't been explicit?'

These examples illustrate the need of a careful balance between following standardised care on one hand and having the flexibility to deviate from procedures when appropriate on the other. This issue of using standardised care to aid rather than control practice was also perceived critical to preventing potential de-skilling. For instance, a nurse researcher gave an example of a setting where a tick box mentality was so dominant that an experienced oncology nurse did not respond to a patient's profound psychological concerns. This opinion leader commented on how nurses in that setting had been … '*deskilled by the system*' that expected them to process patients quickly to achieve targets for waiting times. Further, eight opinion leaders talked about a sense of dissatisfaction and frustration when standardised care meant that health care professionals were not able to use their clinical skills. This sentiment was captured by a general practitioner …

> *'I think there is a danger people don't find protocol driven care enjoyable or maybe satisfying. I would imagine if professionally, I was only ever doing tick box, I wouldn't get as much satisfaction as if I could use my other clinical skills to look at people holistically.'*

In summary, opinion leaders emphasised the importance of preserving flexibility and clinical autonomy in the application of standardised care in order to encourage staff to think creatively, prevent de-skilling and provide effective patient care.

Enabling rather than coercing clinical practice

The previous section highlighted the potential drawbacks when standardised care is applied rigidly. In this section, we focus on factors that influence the extent to which standardised care is perceived as 'enabling' clinical practice. Specifically, opinion leaders discussed negative effects of standardised care when it is perceived as 'coercive' and a means of 'micromanaging' health professionals. These issues complement the above discussion regarding the importance of preserving clinical autonomy because they focus on how standardised care is managed.

There was a sense among some opinion leaders that standardised care may lead to low morale when it is perceived as a means of controlling staff behaviour. For instance, a health visitor in a policy influencing role raised the distinction between standardised care that was supportive with standardised care used as a means of 'micromanaging' professionals …

> *'I think protocols, clinical guidelines and so on should be there to support them in delivering that care, rather than, to micromanage how they deliver that care. Sorry, you have me going. But I think these are the issues that actually affect morale, and it is very difficult to take a step back from risk management.'*

Similarly, a medical practitioner noted the control and power dimensions of standardised care especially when it is perceived as a 'top-down' imposition by individuals who are involved in the design of procedures …

> *'I think there is obviously a power struggle between the people who are devising the guidelines and want to control clinical behaviour that way, and the individual clinicians themselves who don't like having their clinical behaviour controlled.'*

This issue was discussed in more depth by a policy maker who noted the adverse affects on satisfaction and productivity when staff who are expected to use standardised care have not been involved in their design. Top-down imposition and a lack of ownership was perceived to affect patient care as well as fostering a climate of conflict and distrust …

> *'There's the issue of satisfaction and productivity as a result of people who are doing things and they don't believe they should be doing it that way. They may do it resentfully. That itself is going to lead to potentially poor service to the patient and poor relationship with the patient [..] I think the other major adverse impact is if the protocol is designed by someone other than the nurse or the nursing group or the peers, then the relationship with whatever group that designed the protocol is going to become severely strained if the protocol doesn't fit. So where it's doctors designing protocols and nurses following them, clearly there are going to be … So you are then going to get that tension between nurses and doctors and there's also the same similar sorts of tensions you see arising between nurses and management and doctors and management, where management are expecting the protocols to be put in place, but neither of the others are particularly happy to follow. So poorly designed protocols or poorly negotiated and owned protocols lead to conflict. I think that's probably the worst of the aspects of protocols.'*

These examples illustrate that the way that standardised care is designed and managed may influence perceptions of the extent to which procedures are in place to coerce and control or enable clinical practice and subsequently affect staff morale and productivity. Thus, these findings suggest that the benefits of standardised care may be maximised when flexibility in clinical practice is preserved and staff are encouraged to participate and be involved in decisions that directly affect them.

5.2.3 Summary

Opinion leaders discussed several advantages of standardised care for staff, including enhanced autonomy, confidence and well-being. Increasing professional autonomy was associated with the modernisation of health care through expanded roles and specialist nursing practice. Professional confidence stemmed from procedural clarity and sense of security from using evidence-based procedures. This enabled nurses to act autonomously in providing patient care. It also gave nurses and midwives a 'voice' when challenging medical practitioners about patient care.

It was also suggested that standardised care may be particularly useful in building up the confidence of new and inexperienced staff who may not yet have accrued the knowledge to enable them to be effective in all situations.

Nearly half the opinion leaders (15/35) identified drawbacks for staff which related to constraining professional practice and problem solving when standardised care procedures are applied rigidly. There was also concern that standardised care may affect staff morale and productivity when procedures are perceived as a means of controlling

clinician practice. Top-down imposition and lack of staff involvement in the development of procedures were felt to contribute to perceptions of standardised care as a 'negative' factor in the delivery of care.

5.3 Summarising existing evidence and opinion

This chapter has explored the impact of standardised care through existing research in the literature, which has generally positive findings, and the perceptions of opinion leaders, which has offered a more nuanced and complex view of the potential positive and negative outcomes associated with standardised care. This section summarised some of the contrasts identified and draws on organisational research from other areas to locate the issues within wider debates on formalisation in the workplace.

5.3.1 Contrasting accounts of the impacts

There are clear tensions between the largely positive accounts of standardised care emerging from the literature review and the more cautious assessments voiced by opinion leaders.

Much of the variation can be accounted for in the contrasts between, on the one hand, providing sufficient guidance to support expanded roles, increase role clarity and enable higher levels of autonomous working and, on the other, constraining clinical freedom and the ability to use knowledge and experience to inform care giving.

These situations have consequences for patient care and for the ways in which nurses, midwives and health visitors experience work:

- With regard to patients, it appears that standardised care can support improved understanding and communication, however there is also the suggestion that it can lead to more (possibly unnecessary) tests and procedures and restrict the ability to provide individualised patient care.

- With regard to the impact on nurses, midwives and health visitors, standardised care can be associated with better psychological health and improved job satisfaction through increased confidence, better role clarity and enhanced autonomy, but job satisfaction and psychological health could be equally at risk in situations where standardised care restricts clinical freedom and decision making.

5.3.2 Organisational research evidence on formalisation

This debate can also be located in the contrasting assessments of organisational 'formalisation' - the extent of written rules, procedures and instructions - on staff competence, attitudes, and well-being. Formalisation has been extensively researched in the organisational literature and its advantages and disadvantages are well known and will most likely be true of standardised care (Lawton & Burton, unpublished paper). Adler and Borys' (1996, 2000) review of this research literature concluded that two conflicting views of employee outcomes of formalisation emerge. On the negative side, formalisation stifles individual autonomy and creativity, and can lead to less committed, more

dissatisfied, de-motivated and alienated employees. On the positive side, it provides guidance and support, clarifies responsibilities, thereby reducing anxiety and enables employees to be and feel more effective. Hale and Swuste (1998), focusing on safety rules, report similar advantages and disadvantages. On the one hand safety rules promote predictability and uniformity in employees' behaviour and therefore define responsibilities, but excessive prescription can lead to resentment at the loss of autonomy, repressed innovation and learning, and unawareness of new situations.

This body of research suggests that the human impact of standardised care on health professionals has the potential to be profound. The next chapters details the approach taken to testing the impact of enabling or coercive standardised care through findings from a national survey of nurses, midwives and health visitors.

6   Putting 'enabling practices' to the test

In Chapter 5 we describe two discourses pulling in opposite directions about the impact of standardised care on staff attitudes and competencies. Enthusiasts of standardised care promote its ability to support and empower staff in their care giving, while critics describe them as overly bureaucratic, and stifling clinical freedom. The systematic literature review provided support for both positive and negative assessments of standardised care. Positive effects included empowerment, improved communication and teamworking as well as increased satisfaction, commitment and competence (e.g. Gale & Curry, 1999; Stanton & Nix, 2003; Bruton & McPherson, 2004; Dodd-McCue, Tartaglia, Veazey & Streetman, 2005;) whereas negative effects have included deskilling, restricted decision making and constrained use of knowledge and experience (e.g. Manias & Street, 2000; O'Cathain, Sampson, Munro, Thomas & Nicholl, 2004). The opinion leader interviews, and the wider organisational literature examining employee reactions to formalisation also provide contrasting assessments of the impact of standardised care on nurses, midwives and health visitors.

Although the effects of prescriptive rules and procedures have been the subject of many empirical studies in other industries, the nature of the impact of standardised care on nurses, midwives and health visitors has a fairly shallow evidence base. Moreover, the systematic literature review showed that the empirical evidence that exists tends to be anecdotal and often characterised by the use of non-validated measures. This chapter contains the results of the survey investigating the impact that standardised care has on health professionals' quality of working lives, including their well-being, perceived autonomy, self-efficacy (e.g. confidence in their capability to carry out work tasks) and their perceived ability to deliver patient care to high standards.

The survey targets a random sample of nurses, midwives and health visitors and employs reliable and validated measures of staff outcomes. Moreover, in recognition of the ongoing debates about the effects of standardised care, a key objective of the survey was to explore the conditions that may lead to either positive or negative experiences of working under standardised care.

In chapter 6:

Section 6.1 describes a theoretical framework proposed by Adler and Borys (1996) that seeks to reconcile the positive and negative consequences of prescribed rules and procedures. The framework identifies two types of formalisation or written rules, procedures and instructions – enabling and coercive, and provides insight into how the characteristics of the standardised care procedures themselves and the ways in which they are developed are influential in shaping their impact on employee outcomes.

Section 6.2 describes the application of the theoretical framework to study the effects of standardised care on a number of work outcomes for nurses, midwives and health visitors including professional autonomy, self-efficacy and well-being.

Sections 6.3 and 6.4 present the method and the results of the empirical test of the efficacy of the framework in relation to standardised care.

Section 6.5 provides a summary of the results and offers some concluding comments regarding the impact of standardised care on nurses, midwives and health visitors.

6.1 Framework: Enabling and coercive formalisation

Adler and Borys (1996) provide a theoretical analysis that reconciles the contrasting assessments of the impact of formalisation. The framework is useful, not so much in the novelty of what it prescribes, but in its comprehensiveness. For example, Adler and Borys' promotion of the flexible use of rules, and a participative approach to the development and implementation of rules and procedures is prevalent both in the health field and broader organisational literature. The importance of getting the balance right between the consistency achieved by standardising practice and allowing for flexibility so that health care professionals can use their clinical judgement has been recognised both in the health care literature (e.g. Lawton & Parker, 1999) as well as by some of our opinion leaders. Likewise the importance of user participation in change initiatives is a long established principle in facilitating organisational change (Isles & Sutherland, 2001; Moulding, Silagy & Weller, 1999) and in implementing innovations (Greenhalgh *et al.*, 2004). But it is Adler and Borys' overall conceptualisation of enabling and coercive formalisation that is enlightening and provides utility in our analysis of the effects of standardised care.

The divergence of research evidence about the effects of formalisation in the organisational literature, reflects the fact that research has focused on the impact of different degrees of formalisation, but has paid insufficient attention to different types of formalisation (Adler & Borys, 1996). Specifically, Adler and Borys argue that the effects of formalisation on outcomes may be better understood by focusing on the extent to which written rules and procedures are designed to help employees master their tasks and be more effective in their job role (enabling) or to exert control and impose employee compliance (coercive). That is, Adler and Borys argue that potential negative or positive effects of formalisation depend on the nature of the rules and procedures and further propose several 'properties' that constitute, what they argue, 'good' and 'bad' rules. These properties are discussed next.

6.1.1 Features of enabling and coercive formalisation

Adler and Borys (1996) are basically concerned with laying out theoretical and practical guidelines for building better bureaucracies, where enabling or good formalised procedures support high levels performance, assuring quality and consistency but which also promote staff involvement and empowerment. They identify several features that distinguish 'good' from 'bad' rules that can be fruitfully applied to understanding the effects of standardised care.

Repair

One defining feature of enabling bureaucracies is 'repair' where staff are encouraged to identify improvements in the rules and procedures that they are expected to use. That is, enabling bureaucracies encourage staff to voice their concerns regarding the procedures they are expected to use and play an instrumental role in their development, revision and modification. Deviations are seen as opportunities to revise procedures that are not effective (Adler & Borys, 1996) by, for instance, updating the evidence-base underpinning standardised care procedures. Further, the organisation has systems in place to collect and analyse deviations from procedures and modifies these accordingly. Thus, the emphasis is on the idea that organisations with enabling bureaucracies have 'learning diagnostics' in place which are used to address difficulties in the application of standardised procedures and to guide appropriate interventions or modifications whilst employees play an active role in this process. For instance, variance analysis of integrated care pathways, which involves tracking deviations from the plan of care as set out in the pathway, may be used to revise standardised care and ultimately improve the process and quality of care (e.g. Ellis & Johnson, 1999; Atwal & Caldwell, 2002). In addition to refining standardised care, in 'enabling bureaucracies' variance analysis may be a means whereby clinicians can exercise their professional autonomy and deviate from procedures in order to deliver individualised patient care. On the other hand, organisations with a more 'coercive' approach may focus audit activities on monitoring health professionals' behaviour and ensure that it complies with specific quality standards (e.g. Cooke, 2006). In this case, audit is not used as a means of identifying problems and encouraging staff to get involved in improving standardised care. Rather, it is used as a way of checking compliance with procedures and 'disciplining' staff that may deviate from them.

Transparency through staff involvement

A second characteristic of 'good' or enabling rules is that they are 'transparent' in that they codify best practice and ensure staff understand the rationale behind the procedures they use. In an enabling bureaucracy, procedures are not imposed from 'top-down' but rather result from an interactive dialogue between employees and management (Adler & Borys, 1996). Active user involvement ensures users' psychological buy-in to the new procedures and helps identify usability issues that may not be visible to the core development and implementation team. A prototypical example of enabling formalisation is where standardised care is developed in close consultation with staff. Specifically, staff have the opportunity to influence the development of the procedures and the organisation allocates resources to train staff to use standardised care. Piloting of the procedures also enhances usability. Staff involvement is also emphasised in the 12-step guidance to developing and implementing standardised care (MA/NICE, 2002), noted in chapter four. While this has resource implications, poor usability is often expensive. Standardised care must be seen to be reasonable, workable and applying best practice (Parker & Lawton, 2000).

The importance of transparent or usable standardised care procedures is further highlighted by evidence suggesting that lack of guideline adoption by clinicians is often a

result of insufficient training and gaps in skills and knowledge (Moulding *et al.*, 1999). For instance, Grilli and Lomas (1994), based on a review of 23 studies, showed only a 54.5% of compliance with clinical guidelines. Reasons for deviations included a lack of staff understanding of procedures (e.g. transparency) as well as a lack of support for compliance at the local level (e.g. through providing the necessary skills and training). Similarly, health care professionals' involvement in the development of protocols and guidelines is a key component in their successful implementation and diffusion (Moulding *et al.*, 1999). Parker and Lawton (2000), in a study of protocol compliance found that midwives placed considerable faith in protocols. They argued that this positive regard towards protocols could partly be explained by user involvement where protocols …

> *"have typically been developed by, or in close consultation with, those expected to use them so that there is a sense of ownership of the protocols and for the most part, protocols enjoy the trust and respect of the midwives"* (pp. 675-676).

Flexibility

A key feature of enabling bureaucracies is that rules and procedures are used flexibly and staff are encouraged to use their skills and discretion to decide whether they should follow or deviate from them in order to better meet situational demands. Unlike coercive bureaucracies that are rule-bound and use procedures as a means of ensuring conformity in the behaviour of organisational members, enabling bureaucracies encourage individual autonomy and recognise that there will be situations where following procedures may be neither feasible nor desirable (Adler & Borys, 1996). Policy documents (NICE, 2008), practitioners and academics emphasise the need for professional autonomy and flexible use of standardised care, so that the procedures do not replace the knowledge and expertise of health care professionals.

Adler and Borys highlight two other factors that may influence employee outcomes of formalisation that relate to contextual features, rather than the characteristics of the rules and procedures themselves. Both of these features, task routineness and goal congruence, have also received some consideration in the health care literature on standardised care.

6.1.2 Contextual features

Task routineness

Adler and Borys, drawing on contingency theory, point out that negative attitudinal staff outcomes to formalisation are often down to misalignment of formalisation with task requirements. Specifically, activities that are predictable and routine lend themselves to being proceduralised, whereas this is not the case for activities that are complex, non-routine and unpredictable because there will be too many exceptional cases that procedures can not cover (Adler & Borys, 1996; Perrow, 1967). This is particularly important in the application of standardised care procedures given that guidelines or protocols will typically be appropriate for only 80% of patients with the remaining 20% representing 'exceptional' cases (e.g. where a patient may not be responsive to a

particular course of treatment or may present multiple conditions that may not be amenable to treatment by a specific protocol or guideline).

The appropriate match of formalisation to the degree of task routineness is acknowledged in the standardised care literature. For instance, greater discretion is required where care is non-routine and complex, allowing staff to use their knowledge and judgement. These issues were discussed extensively in Chapter 3.

Goal congruence

Finally, Adler and Borys' framework recognises that successful implementation of enabling procedures requires that individual and organisational goals and values are seen as compatible. When individual-organisation goal congruence exists, then individuals are more likely to 'accept' formalised procedures because they will be perceived as a means to an end rather than as a form of organisational control aimed at undermining their sense of professional autonomy. Divergence of goals and values may well result in resistance and negative attitudes towards formalisation. For instance, empirical evidence has shown that medical and nursing cultures are distinct and will influence their attitudes towards rules and procedures. Doctors' training is focused on self-reliance and professional autonomy and fosters a culture of risk-taking. Thus, doctors are more likely to perceive standardised care as restricting their clinical practice compared to midwives or nurses (Parker & Lawton, 2000). The more general point is that the beliefs and values of staff are important to understanding the impact of standardised care, as well as the characteristics of the standardised care procedures themselves (Lawton & Parker, 1999).

In summary, Adler and Borys (1996) argue that bureaucracies may have fundamentally different features that will shape that impact that they have on working practices and key staff outcomes. 'Good' or enabling rules and procedures are conceptualised as flexible guidelines that codify best practice and help employees deal better with the surprises and the unexpected contingencies that they may encounter in their work. Within this enabling type of formalisation, procedures can facilitate problem solving, deviations or mistakes are seen as learning opportunities, they are reported, analysed and acted upon, and employees are encouraged to participate both in the design and modification of the procedures that they are expected to use (Adler & Borys, 1996). Enabling formalisation within organisations involve having members that are empowered and have a 'license to think'.

On the other hand, 'bad' or coercive rules and procedures are designed to monitor and control employees, discourage or even punish deviations and substitute individual skills and judgment. That is, procedures are not designed to help employees with their work tasks but rather constitute a list of tasks and duties to be followed. Further, coercive procedures are imposed 'top-down' and discourage employee participation in the formulation or modification of procedures. That is, coercive rules are difficult to change as revisions are typically viewed as a threat to the existing power balance (Adler & Borys, 1996).

6.2 Applying the framework to standardised care

In light of the above discussion, we argue that standardised care may be expected to have either positive or negative effects on work outcomes depending on the extent to which it is characterised by coercive or enabling features. Specifically, it is expected that enabling characteristics will have positive effects on staff outcomes. That is, where employees are discouraged from exercising their clinical judgement in using standardised care procedures, are not involved in the design and improvement of the procedures that they are expected to use or have a poor understanding of the underlying rationale of standardised care, deleterious effects may be expected in terms of reduced job satisfaction, well-being and reduced quality of patient care (e.g. through an inability to deliver individualised care tailored to the specific needs of a patient).

On the other hand, such negative effects may be offset to the extent that standardised care procedures are perceived as 'enabling' whereby individuals are able or even encouraged to deviate from following pre-specified procedures in managing care. Such deviations would entail a careful consideration of each patient's unique needs thus promoting clinical freedom and judgement. Positive effects on key outcomes may also be expected where staff understand the rationale and evidence underpinning standardised care and are involved in their development and revision or adaptation.

This chapter describes an empirical application of the Adler and Borys framework to examine how key outcomes for nurses, midwives and health visitors are affected by the nature or properties of standardised care.

6.3 Method

6.3.1 National survey: procedure and participants

A postal and web-based survey of nurses, midwives and health visitors was conducted between October 2007 and January 2008. The survey was distributed with the support of the Royal College of Nursing (RCN), the Royal College of Midwives (RCM) and the Community Practitioners' and Health Visitors' Association (CPHVA).

The survey was distributed to 4,000 nurses, 4,000 midwives and 5,000 health visitors. After one postal survey reminder, a total of 2, 711 web and paper-based responses were received. From RCN members, 971 responses were returned, and from RCM members, 1483 responses were returned representing a 31% response rate to the survey. From CPHVA members, 241 responses were returned representing a 5% response rate (see appendix 3a for a detailed description of the survey procedure, the demographic profile of the sample and a discussion of the low response rate from CPHVA members).

6.3.2 Validated and bespoke measures

The questionnaire consisted of 35 questions divided into 4 sections that collected data on various aspects of standardised care, individuals' perceptions of different job characteristics as well as their overall views about their organisation (see appendix 3b for

the survey instrument). Specifically, three groups of factors were examined: enabling features of standardised care, ideological fit and several staff outcomes. These are discussed separately.

Enabling features of standardised care

In order to capture the 'enabling' nature of standardised care procedures we developed new items given that no prior research has applied Adler and Borys' (1996) to examine the impact of standardised care. Thus, drawing on their framework the scales were designed to capture four features of standardised care:

1. Involvement: the extent to which individuals are encouraged to be involved in developing and improving standardised care within their organisation.

2. Repair: the extent to which the organisation collects, reviews and 'learns from' variances or deviations from standardised care procedures.

3. Flexibility: the extent to which staff are able to deviate from procedures in delivering patient care.

4. Transparency: the extent to which staff clearly understand the rationale behind the procedures that they are expected to use.

A total of 15 items were designed to capture these four features of standardised care. A principal components factor analysis revealed three (instead of four) underlying factors that represented the dimensions of involvement, transparency and flexibility. The 'repair' dimension did not emerge as a single factor. However, the scale on 'Involvement in standardised care' captured elements of the 'repair' dimension because it assessed individuals' involvement in both the development and improvement of standardised care procedures.

Table 6.1 presents information on the number of items used to measure each of the 'enabling' features of standardised care, example items and scale reliabilities.

Ideological fit

The role that ideological fit may play in work outcomes such as job satisfaction and well-being was also examined. Ideological fit is defined as the degree to which standardised care matches or is consistent with nurses', midwives' and health visitors' ideals of good patient care. This factor may be an important predictor of work outcomes in light of empirical evidence showing that nurses and midwives experience their work as emotionally rewarding when they are able to work according to their values and ideals (e.g. Hunter, 2004). Given that this factor has not been incorporated in previous quantitative studies on the impact of standardised care, several new items were developed to capture ideological fit. Principal components factor analysis showed that the items captured one underlying factor and further the new scale had a very good reliability (a=.95). The number and examples of items as well as the scale's reliability are presented in Table 6.2.

Table 6.1. Measures of 'enabling' properties of standardised care

Type of 'enabling' property	Number of items	Example item	Scale reliability
Involvement in standardised care	5	Staff responsible for hands-on delivery of care are involved in developing standardised care	0.88
Transparency of standardised care	4	I clearly understand the rationale behind the standardised care procedures I implement	0.91
Flexibility in using standardised care	4	If I judge it in the best interests of a specific patient, it is not mandatory to follow standardised care procedures	0.87

The impact of 'enabling' standardised care procedures and ideological fit was examined in relation to a number of task–related and affective outcomes. These included:

1. Professional autonomy: the extent to which staff have the freedom to determine how they do their job.

2. Individualised patient care: the extent to which staff identify an alternative plan of care when standardised care procedures are inappropriate for the patient.

3. Role clarity: the extent to which individuals know what it is expected of them at work and are able to divide their time appropriately.

4. Self-efficacy: the degree to which staff feel that they have the necessary skills to do their work.

5. Skill use: the extent to which staff feel that their job makes the best use of their skills.

6. Task performance: the degree to which staff are able to provide timely patient care to high standards.

7. Well-being: two dimensions of well-being were assessed, anxiety-contentment and depression-enthusiasm, which focus on the degree to which staff derive a sense of contentment and enthusiasm from their work.

8. Job satisfaction: the extent to which staff are satisfied with their job.

Table 6.3 presents information on the staff outcome measures including number and example items and scale reliabilities.

Table 6.2. Ideological fit measure

Number of items	Example item	Scale reliability
4	Standardised care enables me to work in a manner that is consistent with my ideals of care	0.95

Table 6.3. Staff outcome measures

Work outcome	Number of items	Example item	Scale reliability
Professional autonomy	3	I can decide on my own how to go about doing my work	0.90
Individualised patient care	4	How frequently do you... adopt an approach to care informed by a careful consideration of each patient's needs?	0.75
Role clarity	3	Do you know what your responsibilities are?	0.64
Self-efficacy	3	I have mastered the skills necessary for my job	0.92
Skill use	3	Are you challenged by your job?	0.55
Task performance	3	How frequently do you... provide timely patient care?	0.79
Well-being: Anxiety-contentment	6	During the past month, how much of the time has your job made you feel... tense?	0.85
Well-being: Depression-enthusiasm	6	During the past month, how much of the time has your job made you feel... miserable?	0.87
Job satisfaction	3	I am generally satisfied with the kind of work I do on this job	0.78

Information on all the measures used can be found in Appendix 3a.

6.4 Impact of standardised care on staff work outcomes

This section presents the survey results regarding the impact of standardised care on nurses, midwives and health visitors. In terms of the sample characteristics, approximately 60% of the respondents were hospital and community midwives (27.6% and 16.3% respectively) and staff nurses (16.3%). An additional 22% of the sample were ward managers (7.9%), senior nurses/midwife matrons (7.3%) and health visitors (7.3%). The remaining 18% of the sample occupied various roles including clinical specialists, practice and community nurses as well as researchers/lecturers.

The majority of respondents were female (96.5%) with an average age of 44.6 and their organisational tenure was approximately seven and a half years. The average reported

experience in nursing, midwifery and health visiting was approximately 21 years although for the health visiting sample this was slightly above the average for the whole sample (27 years). Most respondents reported that their Agenda for Change Banding was 5 to 7 with only 6.5% of the sample reporting belonging to Bands 8A and above. Detailed information on the survey responses by different occupational groups and employer types as well as on the demographic profile of the sample is presented in appendix 3a.

In examining the impact of standardised care on work outcomes, two sets of factors were examined. Specifically, we explored the impact of 'enabling' properties of standardised care procedures and ideological fit on a number of task-related and affective outcomes. These questions were exploratory and were tested within a hierarchical regression framework.

The analytical approach adopted involved controlling for any variations in each of the work outcomes arising from the demographic variables age, gender, organisational tenure and job type (e.g. nurses, midwives and health visitors) in Step 1 of the model. The effects of these variables were controlled for because previous research has shown that they have small but stable effects on affective outcomes such as job satisfaction (Blegen, 1993; Adams & Bond, 2000). In Step 2, the enabling properties of standardised care, namely flexibility, transparency and involvement as well as ideological fit were regressed onto each of the outcomes. This procedure was repeated for each of the aforementioned work outcomes resulting in a total of 9 separate hierarchical regressions (see appendix 3a for information on the data analysis).

The results of these analyses are presented in Tables 6.4-6.6. In all cases, demographic variables explained only a small proportion of the variability in the work outcomes examined (this ranged between 1% to 3%).

Further, the survey findings suggest that 'enabling' characteristics of standardised care show differential relationships with the work outcomes examined. It should also be mentioned that we also examined the potential impact of different types of standardised care (such as clinical guidelines, protocols and care pathways) on key staff outcomes. However, the results showed that the presence of enabling features rather than the form of standardised care used was the strongest predictor of staff outcomes. These findings are discussed next.

6.4.1. Individualised patient care

Table 6.4 shows the results of the hierarchical regression analyses for individualised patient care, autonomy, and role clarity.

It can be seen that the strongest predictor of nurses', midwives' and health visitors' perceptions of individualised patient care is the degree to which they feel that they have the flexibility to deviate from standardised care procedures when appropriate. This relationship was positive suggesting that flexibility in the application of standardised care is associated with perceptions of individualised patient care (b=.33, p<.001).

The second strongest predictor was transparency of procedures followed by involvement in standardised care. These findings suggest that in addition to flexibility, clarity of procedures and involvement in standardised care (b=.16, p<.001 and b=.11, p<.001

respectively) also enhance nurses, midwives and health visitors' perceptions of individualised patient care. However, these associations were smaller. The demographic characteristics did not exhibit any significant relationships whilst the regression model explained 19% of the variability in individualised patient care.

Table 6.4. Results of hierarchical linear regression: Individualised patient care, autonomy and role clarity

Model	Individualised patient care	Autonomy	Role Clarity
	Standardised Beta Weights	*Standardised Beta Weights*	*Standardised Beta Weights*
Step 1			
Demographic variables[1]			
	R^2=.00	R^2=.02	R^2=.02
Step 2			
Flexibility	.33**	.29**	.05
Transparency	.16**	.01	.23**
Involvement	.11**	.22**	.11**
Ideological fit	.00	.10**	.10**
	ΔR^2=.19	ΔR^2=.20	ΔR^2=.13

N = 2405-2711 depending on missing values

** $p < .001$

[1]Demographic variables = Age, gender, tenure, job type (nurses, midwives and health visitors)

6.4.2 Professional autonomy

Table 6.4 shows that for professional autonomy the strongest predictors are flexibility and involvement in standardised care. Further, these relationships were positive (b = .29, p<.001 and b=.22, p<.001) suggesting that higher levels of professional autonomy are reported when staff are involved in the development and improvement of standardised care and are able to deviate from procedures when necessary.

Ideological fit also emerged as a significant predictor (albeit its effect was small) suggesting that perceived congruence between staff's ideals of patient care and standardised care is associated with higher levels of professional autonomy (b= .10, p<.001). The combination of these factors accounted for 20% of the variability in professional autonomy.

6.4.3 Role clarity

Table 6.4 shows that transparency is the strongest predictor of role clarity and that further this relationship is positive (b=.23, p<.001). This suggests that procedural clarity is associated with higher levels of role clarity whereby staff are clear about their roles and responsibilities. Involvement and ideological fit also emerged as significant predictors of role clarity and competence respectively albeit their effects were smaller. The regression model containing all the enabling characteristics explained 13% of the variability in role clarity.

6.4.4 Self-efficacy

As was the case with role clarity, transparency emerged as the strongest predictor of self-efficacy (b=.23, p<.001) (see Table 6.5). Flexibility and involvement also showed significant positive relationships with self-efficacy however their effects were small (b=.10, p<.001 and b=.06, p<.05 respectively). The regression model explained 12% of the variability in staff's perceptions of competence.

6.4.5 Psychological well-being

Table 6.5 shows that involvement in standardised care and ideological fit emerged as the strongest predictors of nurses, midwives and health visitors' well-being (e.g. their levels of enthusiasm and contentment as a result of the job). Further these relationships were all positive. That is, staff involvement in standardised care (e.g. the extent to which individuals have opportunities to be involved in developing or improving procedures) was associated with higher levels of enthusiasm (b=.24, p<.001) and contentment (b=.19, p<.001).

Ideological fit also showed significant positive relationships with these outcomes suggesting that when staff perceive that standardised care supports their ideals of good patient care they report higher levels of enthusiasm (b=.22, p<.001) and contentment (b=.20, p<.001) with their job. The enabling characteristics of flexibility and transparency of standardised care did not show significant relationships with these

outcomes. This combination of variables accounted for 18% and 14% of the variability in depression-enthusiasm and anxiety-contentment respectively.

Table 6.5. Results of hierarchical linear regression: Self efficacy and psychological well-being

Model	Self-efficacy	Depression-enthusiasm	Anxiety-contentment
	Standardised Beta Weights	*Standardised Beta Weights*	*Standardised Beta Weights*
Step 1			
Demographic variables[1]			
	R^2=.03	R^2=.02	R^2=.03
Step 2			
Flexibility	.10**	.06	.08
Transparency	.23**	-.01	-.02
Involvement	.06*	.24**	.19**
Ideological fit	.01	.22**	.20**
	ΔR^2= .09	ΔR^2=.16	ΔR^2=.11

N = 2406-2416 depending on missing values
* p<.05 ** p<.01
[1]Demographic variables = Age, gender, tenure, job type (nurses, midwives and health   visitors)

6.4.6 Job satisfaction

As was the case with well-being, staff involvement in standardised care and ideological fit were the strongest predictors of job satisfaction whilst the remaining enabling characteristics did not exhibit any significant relationships (see Table 6.6). Both involvement and ideological fit showed positive relationships with job satisfaction suggesting that staff report higher levels of job satisfaction when they are encouraged to be involved in the development and improvement of standardised care and when they perceive that standardised care supports their ideals of good patient care (b=.21, p<.001 for involvement and b=.22, p<.001 for ideological fit). The regression model explained 15% of the variability in job satisfaction.

6.4.7 Skill use

Involvement was the strongest predictor of skill use suggesting that when staff are involved in the development of standardised care they are more likely to report that their

job enables them to make best use of their knowledge and skills (b=.19, p<.001) (see Table 6.6). Similar relationships were also found for ideological fit and transparency, however these effects were small (b=.12, p<.001 and b=.10, p<.001 respectively). The regression model explained 13% of the variance in skill use.

Table 6.6. Results of hierarchical linear regression: Job satisfaction, skill use and task performance

Model	Job satisfaction	Skill use	Task performance
	Standardised Beta Weights	*Standardised Beta Weights*	*Standardised Beta Weights*
Step 1			
Demographic variables[1]			
	R^2=.01	R^2=.01	R^2=.02
Step 2			
Flexibility	.05	.06	.04
Transparency	.01	.10**	.07**
Involvement	.21**	.19**	.09**
Ideological fit	.22**	.12**	.18**
	ΔR^2= .14	ΔR^2=.12	ΔR^2=.08

N =2405-2416 depending on missing values
**p<.01
[1]Demographic variables = Age, gender, tenure, job type (nurses, midwives and health
   visitors)

6.4.8 Task performance

Finally, the findings suggest that ideological fit is associated with higher levels of perceived task performance (e.g. the extent to which employees feel that they can provide both timely and good quality patient care) (b=.18, p<.001) (see Table 6.6). From the enabling characteristics, involvement in standardised care and transparency of procedures also emerged as significant predictors however their effects were small (b=.09, p<.001 and b=.07, p<.001 respectively). The regression model explained 10% of the variability in staff perceptions of task performance.

In summary, the survey findings suggest that the presence of enabling characteristics of standardised care have significant associations with staff outcomes. Specifically, flexibility to deviate from standardised care procedures was associated with higher levels of professional autonomy and perceptions of individualised patient care. A clear

understanding of the rationale behind the standardised care procedures that staff are expected to follow was the strongest predictor of role clarity and competence in carrying out work tasks.

On the other hand, involvement in the development of standardised care procedures emerged as the strongest predictor of work-related affective outcomes. In particular, staff that are encouraged to be involved in the development or improvement of standardised care report higher levels of job satisfaction, enthusiasm and contentment. Furthermore, a high level of involvement is also the strongest predictor of skill use. A summary of the relationships that emerged from the survey is depicted in Figure 6.1.

6.5 Summary and conclusion

This chapter examined the impact of standardised care on staff task-related and affective outcomes by drawing upon Adler and Borys' (1996) theoretical framework regarding the effects of organisational formalisation. In doing so, we focused on the properties of standardised care and specifically on three key enabling characteristics that may ameliorate potential negative effects of standardised care on working practices. The results show that the presence of 'enabling' standardised care properties, namely flexibility, transparency/usability of procedures and involvement in the development and improvement of standardised care affects staff's sense of self efficacy, role clarity, professional autonomy and ability to deliver individualised patient care. Therefore, in line with Adler and Borys' framework, it is not the use of procedures per se but rather the properties of rules and procedures that are important. In particular, the survey findings suggest:

1. An understanding of the rationale underlying standardised care procedures helps clarify nurses', midwives' and health visitors' roles and responsibilities as well as enhancing their sense of self-efficacy. These findings are consistent with previous research that has shown that nurses and midwives have faith in standardised care because it specifies best practice and provides clear guidance to deliver a high quality service (e.g. Lawton & Parker, 1998; Parker & Lawton, 2000; Dodd-McCue & Tartaglia, 2005). Our case study findings also highlight the importance of usable or transparent procedures for role clarity and self-efficacy. In one of our nursing case studies that focused on the myocardial infarction care pathway, staff interviews revealed that the pathway gave them valuable guidance and made sure that all aspects of care were given to cardiac patients. Similarly, the use of the maternal depression care pathway in one of the health visitor case studies was described as a useful evidence-based tool that gave health visitors confidence in the knowledge that they were 'doing the right thing'. Further, lack of role clarity can undermine organisational efficiency and create inter-organisational conflict (e.g. DiPaola & Hoy, 2001; Rizzo *et al.*, 1970). Thus, a key task for organisations should be to maximise clarity among healthcare professionals regarding standardised care procedures and ensure that they are well-designed and useable. We discuss specific recommendations in Chapter 8.

2. Flexibility in the application of standardised care is associated with increased levels of professional autonomy and perceptions of individualised patient care. These findings

support arguments on the importance of enabling staff to deviate from standardised care when needed in order to guard against negative effects such as restriction of autonomy and encouragement of behavioural conformity that may be to the detriment of patient care (e.g. Carryer *et al.*, 2007; Parker & Lawton, 2000). Thus, organisations should encourage health care professionals to use their professional autonomy by emphasising the importance of maintaining some consistency in the delivery of care whilst at the same time acknowledging that care must be tailored to the needs of the patient. Achieving this balance addresses some of the concerns that were discussed extensively in Chapter 5, namely that standardised care may be overly rigid and constrain health care professionals' use of knowledge and expertise. The finding that flexibility in the use of standardised care enhances staff's perceptions of delivering individualised patient care is very important given that individualised care is a source of job satisfaction for nurses (Forsyth & McKenzie, 2006). Further, individualised or personalised patient care is high on the agenda of government policy emphasising the importance of delivering care that is tailored to the needs of the patient (e.g. Lord Darzi Interim report, 2007; Department of Health publication on 'Creating a patient-led NHS', 2005).

3. Staff involvement in the development and improvement of standardised care is associated with higher levels of job satisfaction, enthusiasm and contentment. These findings are consistent with evidence from both the health care and the broader organisational literature on the impact of participative decision-making on affective outcomes including mental health and job satisfaction. A recent systematic literature review showed that interventions aimed towards increasing employees' opportunities to be involved in decision-making processes had beneficial effects in terms of improved mental health and reduced sickness absence (Egan, Bambra, Thomas, Petticrew, Whitehead & Thomson, 2007). Similar benefits have also been reported in terms of employee job satisfaction and performance (Spector, 1986; Matterson & Ivancevich, 1987). Thus, increasing health care professionals' involvement in the development of standardised care is a key task for organisations. This may take several forms and specific recommendations are discussed in Chapter 8.

The empirical findings presented in this chapter have some limitations that need to be considered. First, the cross-sectional design of the research and the use of self-report measures prevents from making any strong causal inferences. For instance, it may be that individuals who derive a sense of satisfaction and contentment from their job are more likely to seek out opportunities to be involved in the development of standardised care in their workplace rather than vice versa. The finding that the three enabling features exhibit different relationships with work outcomes may suggest that the presence of these features influences outcomes rather than vice versa.

However, future research that adopts longitudinal designs is needed to determine more accurately the direction of causality between enabling features of standardised care and staff outcomes. Moreover, the findings, and in particular the differential relationships between 'enabling' features of standardised care with staff outcomes gives us confidence in the strength of our findings.

Figure 6.1. Relationships between properties of standardised care, ideological fit and work outcome
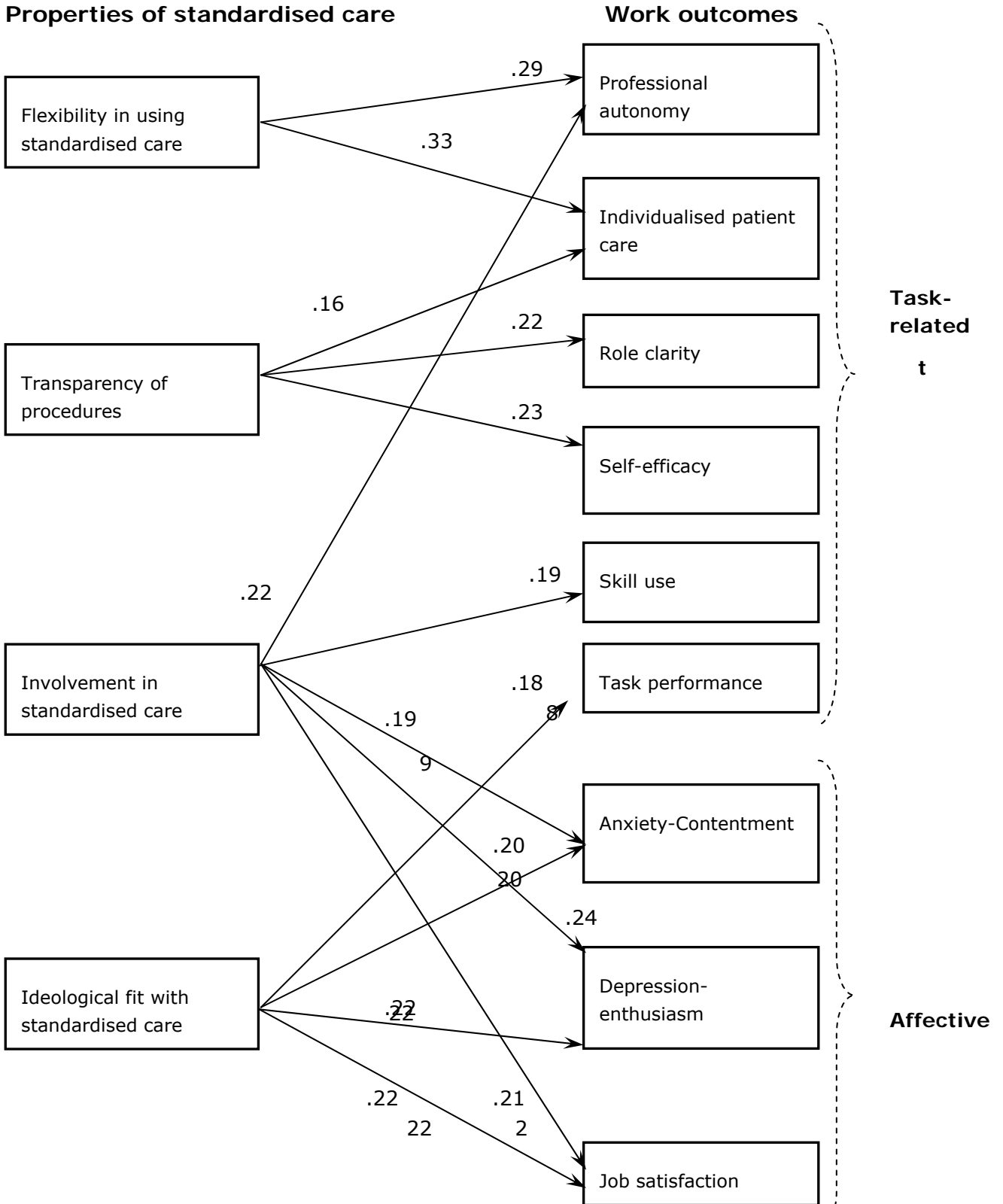
It is not uncommon in large sample sizes to find multiple significant relationships on the basis of small differences. However, the presence of unique, differential relationships between the predictors and work outcomes suggests that our findings are not simply due to chance.

Finally, it should be acknowledged that although the findings were gained from a large, random sample of nurses, midwives and health visitors, this sample is a small representation of the approximately 686,000 nurses, midwives and specialist community public health nurses registered with the National Midwifery Council (NMC 'Statistical Analysis of the Register' report covering the period up to March 2007).

7   Other impacts: costs, patients & quality of care

The third research aim for this study was to understand the impact of nurses', midwives' and health visitors' specific contribution to standardised care on staff and patient outcomes, costs and quality of care. The extensive involvement of nurses, midwives and health visitors makes it difficult to identify examples where they are not involved in developing or adapting these documents. In fact, their role appears so integral to the process of development and implementation of standardised care, that no examples could be identified by this research either of:

• Previous studies that compared the difference between standardised care developed with nursing input and without, or

• Examples from the case studies where standardised care had been developed without nurse, midwife or health visitor input.

Hence, disentangling the specific impacts of their contribution made was made virtually impossible.

Some tentative conclusions can be drawn however about costs, patient impact and quality of care. In this chapter an alternative approach was adopted which involved gathering approximate data about resource costs and synthesising proxy information about patient outcomes. The chapter has two parts. The first part presents cost data gathered directly, where available from three of the five case study sites, and an international literature review was conducted to provide a fuller picture. The second part contains information about the patient perspective and experience of standardised care gained from the opinion leader interviews, the systematic literature review, the national survey and the case studies. The data presented in this chapter is, therefore, more illustrative in nature and highlights areas for further research which are discussed in the final chapter.

In Chapter 7:

Section 7.1 introduces the costs of standardised care and contains the economic literature review.

Section 7.2 presents the findings from three economic case studies, two relate to nursing and one case study is about health visiting.

Section 7.3 gives an overview of the policy drive for a personalised health and social care and outlines how this is conceptualised and operationalised.

Section 7.4 explores patient involvement in the development of standardised care.

Section 7.5 examines standardised care in practice, particularly patient awareness and its use as a tool to support staff-patient communication.

Section 7.6 examines two crucial questions: does standardised care improve patient experience and outcomes?

7.1 Costs of developing standardised care

Uncovering the hidden costs of developing, implementing and monitoring standardised care was one of the main objectives of the research. The resource costs, including the contribution of nurses, midwives and health visitors are labelled as hidden because they tend to be alluded to, but not quantified. For example, one of the opinion leaders, a nurse researcher said …

> '*I think the process of producing protocols is incredibly time and labour expensive. You should not ignore that when you are thinking about the cost benefits of them.*'

The guidance for developing protocol-based/standardised care (MA/NICE 2002) did not mention any cost implications. Only one of 33 UK studies included in the development/implementation review referred to costs. This was Forbes *et al* (2004) who reported asking district nurses to complete a log about the direct and indirect time spent implementing a protocol to assess older frail people with type two diabetes. They concluded that …

> '*the amount of time …. ranged from one hour 20 minutes to one hour 45 minutes, including 30 minutes for follow-up …. cost of each assessment estimated to be £33.00*' (p284).

Given the scant evidence available on costs generally, a systematic literature review was undertaken (for full details see appendix 5). This section summarises the findings from the literature review and the next section reports on the resource costs from three case studies (full details in appendix 6).

7.1.1 Introduction to the economic literature review

When considering the use of standardised care, as with any health care intervention, consideration should be given to its cost-effectiveness. In order for this assessment to be undertaken, the costs and effects of the standardised care 'package' need to be compared to the situation where no standardised care is available. It is also important that the full range of costs and effects associated with the standardised care are evaluated. Grimshaw *et al* (2004) recommend considering three costs related to:

1. development,

2. dissemination/implementation and

3. the treatment effects/costs related to behaviour change in any economic evaluation of clinical guidelines.

In their review of 235 'rigorous' evaluations of guidelines, published prior to 1999, only 63 (26.8%) reported any cost analyses, and only four (1.7%) reported the costs of development and dissemination/implementation.

This literature review was intended to assess how standardised care has been evaluated within cost-effectiveness analyses and also to assess the costs of development and implementation. The terms were defined as:

- Development: resources needed to devise the standardised care package, for example staff time for meetings, and literature reviews.

- Implementation: resources needed for staff to operationalise the standardised care for example, educational or training programmes, and the costs of monitoring, through audit and data analysis, but excludes treatment costs.

- Consequences: refer to the costs of providing care, and any impact it may have on subsequent contacts with the health service.

7.1.2 Systematic literature review method

A series of broad and specific search strategies were employed. The NHS Economic Evaluation Database (NHS EED) was searched for economic evaluations with either 'guideline' or 'protocol' in the title to ensure that these forms of standardised care were central to the evaluation. The searches identified 42 articles, all of which were retrieved. One was subsequently excluded from the review as costs were not valued in monetary units (Konski *et al.*, 1997) and the other was in a foreign language (Del Cura, Oleaga, Grande, Vela, & Ibanez, 2001). This literature review, unlike the others about development/implementation and impact, was not limited to nurses, midwives and health visitors. This was to gain a comprehensive picture about what is known about the cost of standardised care.

The full papers were reviewed and data were abstracted on the context of the evaluation (e.g. country, condition, aspect of care), the presence of cost information on the development, implementation and consequences of standardised care, and the conclusions relating to costs. The data from the 40 papers are summarised in table 5.1 in appendix 5.

7.1.3 Findings: little evidence about costs

The majority of papers (36/40) reported the consequences of standardised care. These studies typically reported the total costs, but in many circumstances concentrated on the single aspect of care that was the focus of the protocol or guideline. For example, when examining the use of continuous neuromuscular blockade in critical care patients, MacLaren *et al* (2001) only looked at the acquisition costs of drugs.

Only four studies contained data about the development and implementation costs (Hoeijenbos *et al.*, 2005; Robling *et al.*, 2002; Schmidt *et al.*, 2002; Tilley *et al.*, 2005). Differences in methodology and varying degrees of details in the papers make it difficult to synthesise and a description of each is given here.

Robling *et al* (2002) estimated the costs of seminars and feedback as part of their evaluation however, these were not described in any great detail. Resource use was not detailed which means we are uncertain about what items are included in their estimated costs. In contrast to the majority of other studies in Table 5.1 in appendix 5, Robling *et al* (2002) did not include the total costs of care that were a consequence of the protocol: their costs refer just to telephone access to imaging, and not to the cost of the imaging and related care. Also, Robling *et al* (2002) did not include the costs of developing the guidelines in their estimates.

In contrast, Tilley and colleagues did include the costs of guideline development within their costs, however, these can not be disentangled from the total costs used in their analysis (Tilley *et al.*, 2005).

The studies by Hoejinbos (2005) and Schmidt (2002) gave more detailed breakdowns of costs relating to implementation although the costs were derived in different ways. Hoejinbos (2005) gathered detailed information on items of resource use and produced a cost of implementation through this 'empirical' approach and Schmidt (2002) generated their costs through professional opinion of what 'would be needed.'

Several studies implicitly identified resource use relating to development and implementation, but these were not included in the economic evaluation. For example, Jones *et al* (1996) observed that continued efforts at staff education and reminders in newsletters were used during protocol implementation (Jones *et al.*, 1996). The absence of these costs in studies appears to be due to the financial focus of the studies, with the American studies in particular concentrating on charges or budgets. Consequently, costs predominantly relate to those where there are direct financial consequences associated with the standardised care.

Overall, the evidence from the literature review suggests that data on costs is neither comprehensive, nor consistently gathered and as a result, little can be concluded about the cost of standardised care development and implementation in health care in the UK or other countries. The next section reports on evidence from three case studies where it was possible to estimate costs based on retrospective data.

7.2 Introduction to the economic case studies

Anecdotal evidence suggests that substantial time and effort is required to develop standardised care, although there is very little information about the resource costs. The literature review showed that few economic evaluations gathered data on the costs of development and implementation. From those studies that were available, staff costs are perhaps the largest resource cost. In the case studies, the aim was to assess the costs of

development, implementation and monitoring, by mapping out the types of staff involved and how they contributed throughout the development process.

7.2.1 Methods

Three case study sites, each with a well-established form of standardised care, were used: two related to nursing and one was about health visiting. The case studies were:

1. A nursing case study using a locally developed integrated care pathway for myocardial infarction in a district general hospital

2. A nursing case study about the adoption and roll-out of the Liverpool end of life care pathway in a district general hospital.

3. A health visiting case study about a locally developed protocol for maternal mental health that was being updated to harmonise use across a new Primary Care Trust and also to align with new NICE clinical guidelines.

The aim of the economic analysis at the case studies was to provide insight into the scale of costs, based on identifying who was involved and quantifying their level of input. Data was collected from two sources: in-depth interviews with the operational lead and documentary analysis. The documents were the minutes of team meetings and cost estimates for external services. The following data was extracted:

1. All the team members, their grade and their professional grouping.

2. The meetings that took place, how often and their duration.

3. The training that was involved, who and how many people attended the training sessions, and whether there were any supporting documents.

4. How many drafts of the pathway there were and if there was any, who were involved in monitoring it, and any supplementary documentation.

This produced information about the total amount of time the process took split by staff groups (managers and administrative staff; medical consultants; nurses, midwives and health visitors; other medical staff such as paramedics) and by year. Full details of the analysis are in appendix 6.

7.2.2 Nursing: MI care pathway

The findings are based on documentary evidence and interviews with two operational leads for this integrated care pathway for patients with a myocardial infarction (MI). Documentary evidence from the minutes of 19 meetings held between 2000-2005 was analysed. The minutes consisted of full team meetings as well as subgroup meetings and they highlighted the tasks assigned to different individuals as the pathway progressed over six years. The numbers of meetings per year are show in Table 8:1. This shows a consistent number of three-four meetings each year until 2005, when only two meetings were held.

Table 7.1. The number of meetings held over the six year period to develop, maintain and review the myocardial infarction care pathway.

Year:	2000	2001	2002	2003	2004	2005
Number of meetings:	4	4	3	3	3	2

The profile of activity over the six years in shown in Figure 8.1. The greatest activity occurred in the first two years, it then reduced and there continues to be staff input eight years after the protocol was developed. In the first two years, managers and nurses (groups 1 and 3) spend the majority of days on the pathway. This represents the time spent on the development by the pathway coordinator and the lead nurse on the pathway. A one day stakeholder event was held in the first year and attended by approximately 60 people. This explains the large number of days represented by other staff (group 4) in year 1.

Figure 7.1. Total number of days per group by year for the MI case study
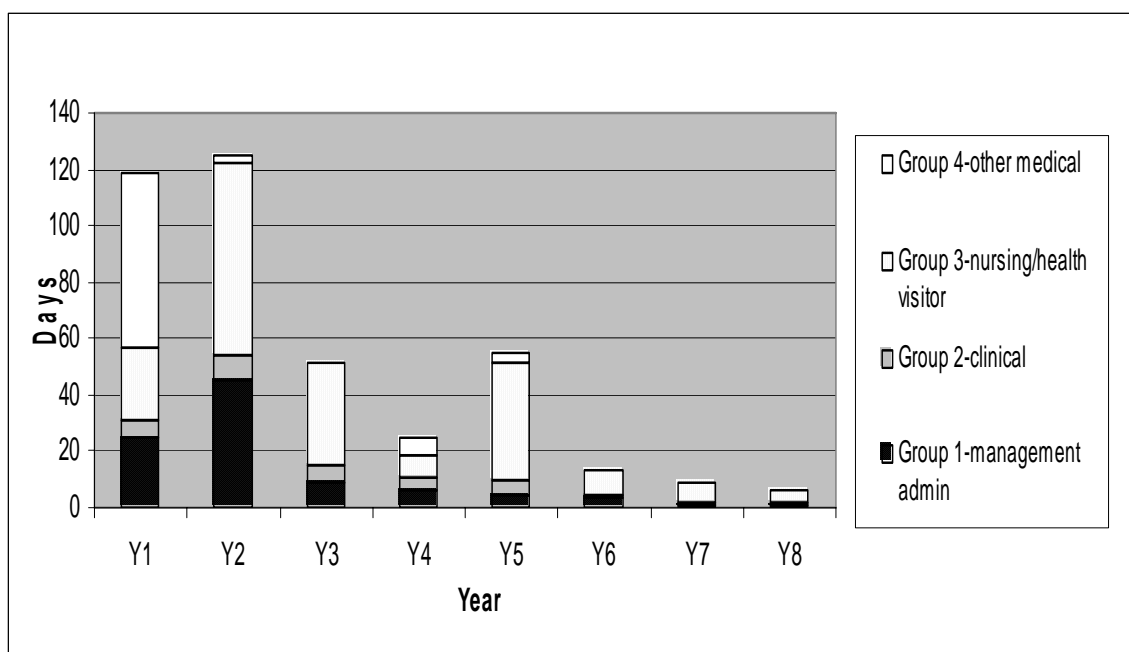
During years two to eight the pathway was implemented and monitored. Several audits informed the redrafting of the integrated care pathway. There were training sessions for nurses on different wards and also for doctors. Supplementary training materials were prepared in line with training needs. Initially, the pathway was implemented in the Coronary Care Unit (CCU) and another cardiac ward. In both these settings, the pathway has become embedded in routine practice, being described and used as "*standard*" for patients with an acute myocardial infarction. There have been several attempts to roll-out the pathway to all the acute medical wards in the hospital, but this has proved challenging.

The overall costs per year are shown in table 8.2. After discounting (see Methods), the total cost of the pathway was £100,823. The largest share of this was taken up by the monitoring phase costing approximately £42,252 (42%) of the total cost with implementation and development costing £31,016 (31%) and £27,555 (27%), respectively.

Table 7.2. Overall costs, when combined with daily staff costs, of the development, implementation and monitoring of the MI care pathway.

Year:	1	2	3	4	5	6	7	8
Costs :	£27,555	£33,746	£15,875	£8,854	£15,501	£3,616	£2,661	£2,169

7.2.3 Nursing: Liverpool Care Pathway

The second nursing case study focused on the Liverpool Care Pathway (LCP) for end of life care. The economic analysis was based on an in-depth interview with the operational lead who had been involved from the beginning. A task list, identifying the key events from 2001 until 2008, was created. External funding was obtained to employ a pathway co-ordinator, in the first instance for one year, and then for three years, from two different funding sources. The majority of the resources used were tied to the funding of the pathway co-ordinator. The estimated costs are shown in Figure 7.2. The activities undertaken in years four to five, and years six to eight, were aggregated because of missing data.

In the first three years, time was spent learning about the Liverpool Care Pathway (LCP), piloting it and writing the funding bid. Little work was required in these initial stages to adapt the pathway to their setting. In the fourth year there was a large increase in costs when the pathway co-ordinator post was filled and additional resources were dedicated to the pathway to deliver training, champion the pathway and manage the co-ordinator. The main task was training nursing and medical staff to use the end of life care pathway, as the document could only be used on wards that had completed the training. Other members of the Palliative Care Team also supported the training sessions. The time that the nurse, who was pathway co-ordinator, spent on the pathway is highlighted by the high proportion of days shown in years four to five and years six to eight.

The final three years were the most costly. In addition to salary costs, additional costs were incurred in updating of the pathway, delivering the requirements for the national audit, training, producing supporting documentation and line management of the pathway co-ordinator. Most of the resource costs were related to the pathway co-ordinator post and other supportive activities. Most of the tasks were completed by nurses (group 3).

Figure 7.2. Total number of days per group by year for the LCP care pathway
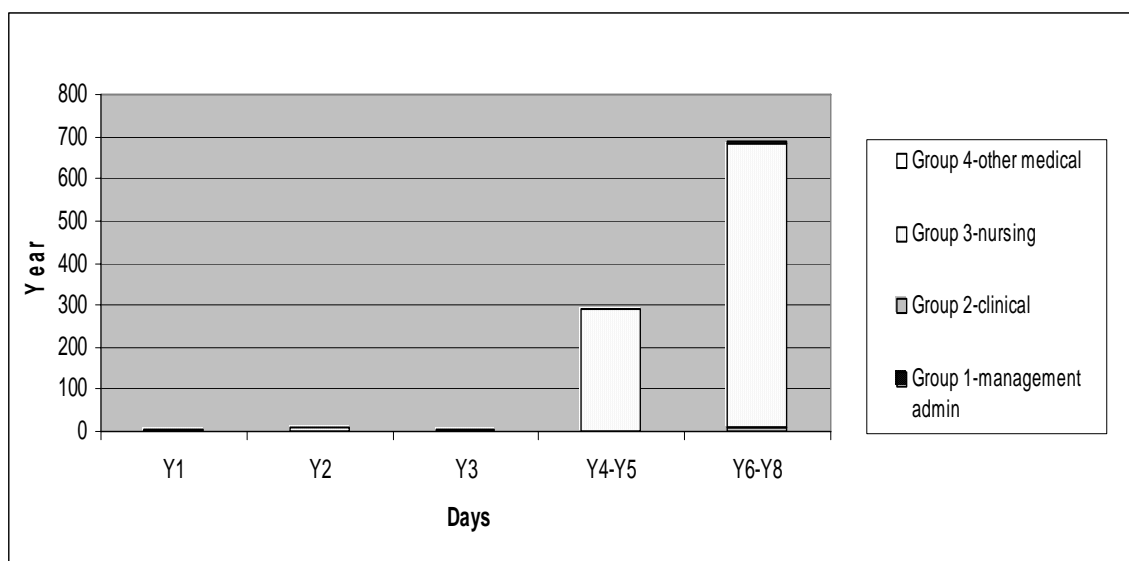
Table 8.3 shows the estimated overall cost of the pathway, derived from combining the staff costs with the days of pathway related work. The approximate costs of £117,000 for years 6-8 when the LCP was being implemented in the District General Hospital are noteworthy because they represent the most costly period across the three case studies.

Table 7.3. Overall costs for the adoption and roll-out of the Liverpool end of life care pathway.

Year:	1	2	3	4-5	6-8
Costs:	£1,383	£2,190	£691	£45,273	£117,688

With the limited amount of detail that was available to us the total cost of the pathway, after discounting to produce a present value, was £140,985 with each phase of the pathway costing the following: development = £1,383 (1%), implementation = £133,368 (98.55%) and monitoring = £6,234 (0.5%). This shows that nearly all of the costs fall under implementation, which makes sense as training played such a major role in the successful implementation of this pathway. Indeed no member of staff was permitted to use the LCP documentation before undergoing formal training. Likewise, development costs are so low as the pathway had been previously developed elsewhere and underwent very little adaptation to the case study site.

7.2.4 Health visitor: maternal mental health protocol

In the health visitor case study, information was obtained from an in-depth interview with the operational lead and documentary analysis. The documentary evidence comprised the minutes of meetings, the costings for an external trainer and e-mail correspondence about the training sessions. A five page task list was derived from collating the two sources of information. Table 7.4 contains an extract about the implementation tasks associated with training. This shows the detailed activities, the

time intensive and diverse resource use involved in preparing health visitors, midwives, nursery nurses and others to use the maternal mental health protocol in a primary care trust.

Table 7.4. Training plan associated with the launch of the protocol in 2006.

Component tasks associated with training plan for implementation
Identifying date and external trainer
Preparing case studies for launch
Agreeing presentations at training day
Consulting health visitors and midwives about training plan
Detailing health visitors and midwives training dates
Preparing training packs
'Mop up' training for health visitors unable to attend launch training and detailed training
Specialist practice mentors to see though cascade training
Provide refresher/update training annually
Provide additional training and develop training packages for the breast feeding network, Homestart volunteers and nursery nurses, including competency based training for nursery nurses

A total of 15 meetings were held over a five year period and are shown in table 7.5 The minutes dated from 2004, for the first meetings of the core protocol group, to the most recent meeting in January 2008. They highlighted the tasks assigned to different individuals in the group as the protocol progressed over its different stages. The 15 meetings were supported by documentary evidence.

Table 7.5. The number of meetings held over the five year period to develop, maintain and review the maternal mental health protocol.

Year:	2004	2005	2006	2007	2008
Number of meetings:	3	4	3	4	1

This health visitor case study showed the complexities of the protocol development process. It went through three stages, although in this analysis we account for the final two stages. In the first stage (which precedes the time frame of our analysis) a protocol was developed, but was not fully implemented. In the second stage, starting in 2004, this pre-existing protocol was updated and then implemented. The final stage, follows a major structural change, with several PCTs merging into one in October 2006. This resulted in a plan to harmonise the protocol for maternal mental health across the new trust and also to incorporate new NICE guidance into the protocol. This means that there

are two distinct parts to this case study over the period (2004 – 2008) which is reflected in the results.

When estimating time inputs, the team was split into core members and non-core members, based on information from the operational lead and who also attended the meetings. This information was used to approximate how much time each group spent overall on protocol-related tasks, deducing that core members spent on average two hours a week on protocol-related tasks whilst non-core members spent two hours a month. From this we were able to estimate the costs, which are shown in Figure 8.3.

Figure 7.3. Total number of days per group by year for the health visitor site
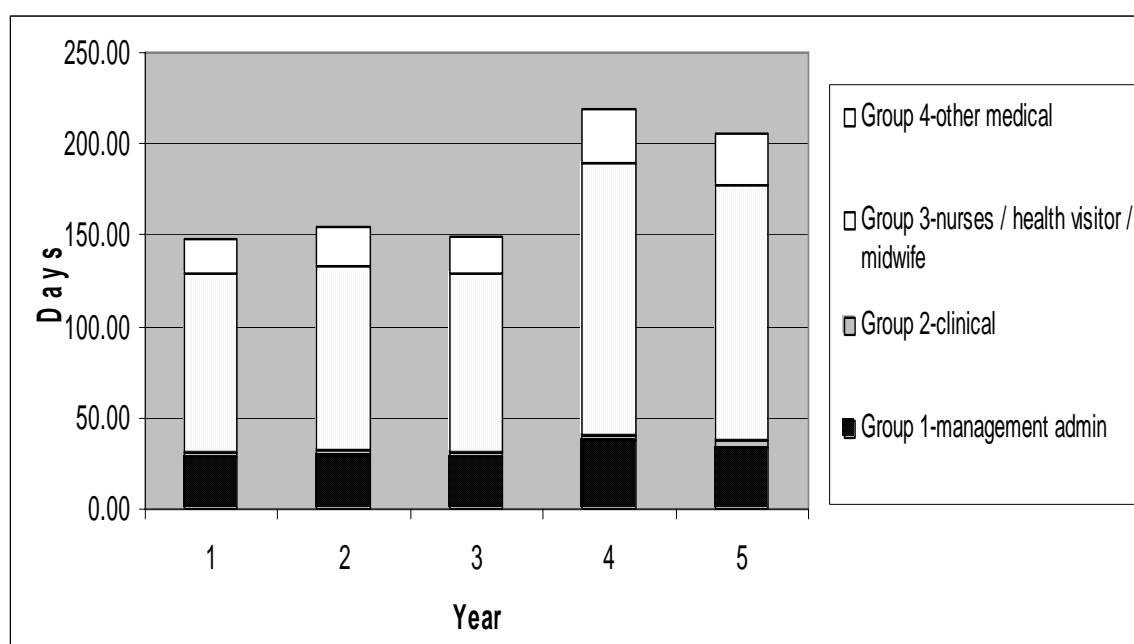
Figure 8.3 shows a steady profile of activity over the years with a sharp rise in activity, and costs, in years four and five when the new PCT was established and the protocol was reviewed with the view to harmonisation within the new organisation. Most activity was undertaken by health visitors (members of group 3) and they represent the greatest pool of resources. There was very little input from individuals that would fall into group 2 (medical consultants).

The approximated total cost of the protocol is £176,098, with development, implementation and monitoring costing £65,329, £110,769 and £0.00 respectively. It should be noted however that over the 5 years the detail of information available did not allow the identification of resources dedicated to monitoring. We were only able distinguish between development and implementation costs, with the former covering years 1 and 2 and the latter spanning over years three to five.

Table 7.6. Overall costs for the development, implementation and review of the maternal mental health protocol.

Year:	1	2	3	4	5
Costs:	£33,150	£34,471	£34,387	£47,920	£45,101

7.2.5 Discussion

The case study work showed the difficulty in identifying staff time relating to the development, implementation and monitoring of standardised care. This data is not routinely collected, and can only be constructed through a careful analysis of documentary evidence in tandem with detailed interviews with key personnel. More accurate estimates require prospective data collection.

Each site produced a different profile of costs. This was for a number of reasons. Firstly, the methods and data available at the three sites differed slightly. Secondly, one nursing case study was about the local development of the myocardial infarction (MI) care pathway, whereas the other two used a pre-existing pathway and protocol, albeit with different origins. The MI care pathway shows that development is associated with the greatest amount of input, whilst the other case studies do not. Thirdly, local factors play a large role in resourcing the process. This is highlighted in the nursing case study about the Liverpool end of life care pathway, where there was low staff input until external funding was obtained for a pathway co-coordinator. In the health visitor case study, the increase in costs were associated with the PCT restructuring which precipitated amendments to the protocol.

The high cost of standardised care development seen in the MI care pathway, estimated at £100,823, is noteworthy because within the literature review, such costs were the least researched of all costs. This case study shows that costs can be significant, and the exclusion of these costs is potentially a major flaw in any evaluation.

The results show other important features. Of particular note is the level of staff input and costs; hundreds of days of staff time are required, and whilst this reduces over time when the protocol has become embedded in routine practice (as in the MI care pathway), some staff time is still required to manage and up-date the pathway. Also, other events may trigger peaks in staff input, for example, rolling out the protocol following organisational restructuring, or the issuing of relevant NICE guidance. It appears that once the protocol is in place, its associated machinery needs to be revived when changes occur in, and around, the standardised care.

In all three case studies, nurse and health visitors played a prominent role. Whilst we can make no claim as to the generalisability of this finding – in fact, we may expect a bias in favour of this finding as sites were recruited on the basis of their interest in nursing/midwifery/health visiting – it highlights the important contribution of these staff groups.

7.2.6 Summary of the economic evidence

This section has highlighted both the paucity of existing evidence about the costs of developing standardised care, and also the difficulty in obtaining such information as the resource costs are not routinely collected. The case study work provides, for the first time, some 'best guesses' about costs, albeit derived from limited, retrospective data. Most cost was incurred when rolling-out an existing pathway within a district general hospital, with the first two years costing approximately £117,000. The average, estimated cost for each standardised care was £139,000 across the three case studies. Such information is vital for policy makers, commissioners, managers and practitioners.

The systematic review of economic data did not identify any studies that looked at all three stages of standardised care considered necessary for a comprehensive economic evaluation (Grimshaw *et al.*, 2004), i.e. development, implementation/dissemination and treatment consequences. Only four studies in the review conducted for this research examined the costs of development and implementation   This clearly demonstrates a knowledge gap in relation to the costs involved in the development and implementation of standardised care. It also confirmed Grimshaw *et al*'s (2004) systematic review, which found that only four from 235 studies had estimated the costs of developing and implementing clinical guidelines.

The literature review highlighted some methodological problems. For example, the fact that 'implementation' is sometimes identified as the cost of the intervention, as opposed to the costs of preparing the staff and organisation for the initiation of the change, the standardised care. Another problem is that studies frequently refer to development and implementation, but this only takes place in a general narrative, without any attempt at quantifying the amount of resource devoted to it. Consequently, whilst a superficial scan of the literature may suggest that implementation costs are widely estimated, this is not confirmed by an in-depth appraisal.

There are other costs not mentioned by Grimshaw *et al* (2004) and which were not covered in any of the literature we identified. These are cost gains, or losses associated with changes to skill mix as a result of introducing standardised care, and softer costs in terms of staff well-being, productivity, skill use and turnover if standardised care is poorly implemented or imposed, or does not work as envisaged.

It was possible to provide some illustration of costs, based on limited, post-hoc data from the three case studies. The cost data presented here represents a 'best guess' based on what was available from the case study sites. They quantify the large amount of staff time that is required for the development and implementation of standardised care. When interpreted in tandem with the economic literature review, it raises questions about the cost efficiency of this way of working. It also appears that in a rapidly changing healthcare environment, additional costs are generated for pre-existing documents, as they are adapted to incorporate many of these changes (e.g. organisational restructuring or new NICE guidance).

7.3 Patient experience and outcomes

In the second part of the chapter, the focus moves from costs to the patient experience and outcomes. Policy and conceptualisations about personalisation, patient choice and control are presented first to set the scene. This is followed by proxy information, gained from the opinion leader interviews, the national survey and the case studies, about patient awareness of receiving care in accordance with evidence-based standards. The crucial question about whether standardised care improves patient outcomes is also examined. The process and outcomes of standardised care are likely to give insights into quality of care.

7.3.1 Policy directions: patient choice and control

Government policy is promoting the involvement of patients and the public in decisions about the planning, design, development and delivery of local service, with the aim of improving health and social care. In 2005, the Department of Health published Creating a Patient-led NHS – Delivering the NHS Improvement Plan which stated the government's ambition to change the whole system so that the NHS provides more choice, more personalised care and empowers people to improve their own health. Similar sentiments were expressed by Lord Darzi in his interim report of the fundamental review of the NHS. He envisions creating a …

> 'personalised NHS (that) must be tailored to needs and wants of each individual, especially the most vulnerable and those in greatest need, providing access to services at the time and place of their choice' (Darzi, 2007: p23).

There is a parallel policy drive about person-centred care and independent living in social care. The provision of direct payments for social care through the Direct Payments (Community Care) Act in 1996 and individual budgets are two powerful ways of transferring control to patients because they hold the budget and purchase their own services (Alakeson 2008). In December 2007, a ministerial concordat entitled 'Putting people first: a shared vision and commitment to the transformation of adult social care' was published. The concordat describes the key elements of a personalised adult social care system that is …

> 'fair, accessible and responsive to the individual needs of those who use services and their carers'

and where people are supported to …

> 'exercise maximum control over their own life' (p2).

7.3.2 Conceptualisations of choice and control

Choice and control feature in the discourses about patient-led and patient-focused interventions. The meaning and operation of these concepts are relevant. For example, Fotaki *et al* 2007 in a scoping literature review about consumer choice linked to efficiency, equity and quality, noted the complexity of choice, and highlighting that there

is little evidence that giving patient's greater choice, in itself, improves the quality of their care.

Coulter and Ellins (2006: p6) conclude that consumer choice and voice underpin patient-focused interventions which encompass the contribution of individuals to their own care as well as their collective contribution to quality improvement initiatives. Following a literature review, they categorised patient-focussed interventions into seven groups: health literacy; clinical decision making; self-care; patient safety; access to health advice; the care experience; and service development.

7.3.3 Standardised care and/or personalised care?

Standardised care could complement or counter the personalised care agenda. Standardised care could support patient-focused interventions in two ways:

1. by improving health literacy through the provision of patient versions of care pathways or clinical guidelines, and

2. through patient involvement in the design, development and evaluation of standardised care as a service development.

Alternatively, standardised care may be seen as a mechanism for limiting patient choice and control because care is delivered according to a standard that is applied to everyone. This is counter to two of the areas that matter most to patients which are:

1. '*treat me as a person, not a symptom*' and

2. '*work with me as a partner in my health – not just a recipient of care*' (Department of Health 2007).

7.3.4 Patient involvement and voice in decision-making

There are many different ways of involving patients, their carers and the public at a strategic level in health care. For example, Pawson *et al* (2003) define four levels of participation: passive; consultative; active; and ownership. Fudge, Wolfe & McKevitt (2008) describe differences been professional and patient/user groups about such involvement, with professionals viewing involvement as an exercise in democracy or as a way of complying with policy directives; whereas patients were motivated by the …

> '*desire to improve services, social opportunities, increasing knowledge of stroke and accessing services*' (p315).

Patient involvement was promoted in the Guidance published to support protocol-based care (MA/NICE 2002); it was described as …

> '*essential in planning service improvements*' and that '*it is extremely important that they should be actively involved in the decision-making process*'…

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about the development of protocol-based care (MA/NICE 2002: p5). A number of mechanisms for patient involvement are suggested, including having patient representatives and interest groups on the development team, the Patient Advice and

Liaison Service (PALS), a patients' forum, patient associations and using complaints and feedback. The Guidance also suggests producing a summary of the protocol for patients.

7.4 Patient involvement in the development process

Despite the policy rhetoric on patient involvement, reality seems to be somewhat different. Few studies were identified that have investigated patient or public involvement in service development or the patient perspective on developing standardised care. A Cochrane review published in 2006 did not identify any comparative studies about consumer involvement in the development of clinical practice guidelines (Nilsen *et al* 2006).

There are some qualitative studies about patient involvement in local and national standardised care. For example, Hughes (2002) describes the involvement of patients in the development of an integrated care pathway for colorectal cancer in one Trust. Quennell (2003) reports a qualitative study about the involvement of patient/carer representatives on technology appraisals produced by NICE, concluding that the …

> *'popularist thrust of participation may be at odds with instrumentalism of evidence-based medicine' (p40)* …

because of concerns about the way in which patient knowledge was handled, weighed and valued when matched with scientific knowledge from randomised controls trials.

This section synthesises findings from the opinion leader interviews, the systematic literature review and the case studies, to explore the reasons for, and the factors that influence patient involvement in the development process.

7.4.1 Evidence about involvement in standardised care

Only one of the 33 UK studies included in the development/implementation review, reported involving patients in the decision making process. Wainwright *et al* (2003) describe how a patient representative support group instigated a protocol that was intended to improve the consistency of diagnosis and treatment of women with symphysis pubis dysfunction. Women were also members of the development group and co-authors of the paper. This example reflects active participation and ownership with the women being instigators and equal partners in the development process.

Seven other studies illustrate a mainly passive approach to patient participation. Six studies described producing patient information leaflets as part of the implementation strategy (Smith & Callaghan 2001, Wood 2002, Porrett, Knowles & Lunniss 2003, Wainwright *et al* 2003). One was produced in the form of a bookmark (Kinley & Brennan 2004) and one involved revising existing patient information (Baird *et al* 2001). In addition, Haw & Kitching (2000) reported consulting some patients by questioning them

about the information they received about prevention. Patient information can play an important role in the development of patient information as demonstrated in a recent Cochrane review. Nilsen *et al* (2006) found that information leaflets developed with patients were more relevant, readable and understandable to patients than those developed without their input.

Less than half of the opinion leaders (15/35) mentioned the involvement of patients, their carers or patient organisations in the development of standardised care. Three informants - a health visitor, a midwife and a nurse – had direct experience of developing standardised care with the active involvement of patients. All the examples relate the health of women around child bearing. Patient organisations were most frequently identified as the source of contributors, and those named were the National Childbirth Trust, the Maternity Users Alliance, and SureStart. User forums in Trusts, such as Patient Advice and Liaison Services (PALS), and the Managed Clinical Networks in Scotland were also cited.

The most striking example of a woman's active involvement was where an employer had released a member of staff to join the authoring group responsible for developing a care pathway for maternal mental health. The health visitor described the employing organisation as …

> 'very supportive. They actually gave her time away from work to attend (the working group), which was fantastic.'

Patient involvement in the development process was reported in three of the five case studies. The three examples also related to women, one was about midwifery-led care guidelines and two were about maternal mental health. Women were involved actively, as members of the development group and were consulted about the design of patient information leaflets about post natal depression. They were also involved indirectly, with qualitative studies reporting their experience of maternity services, valued as evidence that informed the recommendations for the midwifery-led care guidelines.

There was no involvement of patients in the two nursing case studies. One involved adopting a pathway - the Liverpool end of life care pathway – that had been developed elsewhere. The second case study was about an integrated care pathway for myocardial infarction. The operational lead indicated that, because the pathway was a tool and record for staff, it was not really appropriate or possible for patients to contribute as …

> 'they are not going to fill them in … I am unsure what part they would contribute.'

Overall this data provides little evidence that patient involvement has increased with the advent of standardised care. The next section considers perceptions from the case studies and opinion leader interviews about the reasons for involving patients.

7.4.2 Reasons for involving patients

Quality improvement and person-centred care were the two main reasons given for involving patients by the opinion leaders. A health visitor described women as "*allies*" and a midwife explained that …

> '*the users were incredibly helpful because they really made you think … and to try to really critically come to grips with what is important.*'

A nurse in a policy-making role, promoted the engagement of patients to help make health care more person-centred, saying that patients …

> '*are in there challenging the traditional approach of 'I am the clinician, I know best' and therefore you get a far more robust journey defined for the patient, a far more flexible journey that is able to respond to individual needs.*'

Individual patients or patient groups were perceived to be motivated by wanting …

> '*to see things improve for others*' (health visitor).

However, equal mentions were made of why it was not appropriate to include patients at the design stage. Five opinion leaders spoke about the practical problems of recruiting patients, especially finding people with the right skills, recent experience and representing a range of views who had the …

> '*spare time to work for free for the NHS on protocols.*'

One admitted to having a…

> '*jaundiced view on participation …. there's a very narrow group of people who want to participate.*'

A nurse researcher/practitioner described it as a struggle to get meaningful patient involvement in research and practice development initiatives. Two opinion leaders questioned the rhetoric of patient-centred care because of the difficulties of engaging patient involvement, especially for topics about pure clinical practice.

Opinion on the inclusion of patients at the development stage is mixed, and points to the possibility that it may be a more or less appropriate activity, dependent on the nature of the standardised care being developed. The questions raised are:

- Is patient involvement always desirable/appropriate/feasible?;

- If so, in what capacity?; and

- On which parts of the standardised care under development?

7.4.3 Factors influencing patient involvement

Three factors were identified in the case study and interview data that appeared to influence the involvement of patients in the development process. These were the culture of the healthcare setting, the development process and the ability of the leader to overcome the obstacles to patient involvement.

The importance of the culture in healthcare was highlighted by a health visitor with experience of primary and social care, who commented …

> 'If you look at the research evidence within social care, there is a strong culture of working with, and alongside, service users.'

Second, the extent to which the process of development anticipates or plans for patient involvement was highlighted by a nurse, who noted the difference in approach to patient involvement between NICE and other groups that develop guidelines, saying that with NICE …

> 'patient involvement is part of the whole development process'

however, with other forms of standardised care …

> 'it was not something that we commonly came across.'

The third factor was the ability of the local leader to engage with patient organisations, to provide ways whereby patients could offer their insights into the whole patient journey and make suggestions for improvement. Opinion leaders, who had done this, reported negotiating with members of the multi-professional and/or agency teams about recommended service changes and then giving feedback on progress to the patient representative(s). A health visitor outlined how she had used focus groups, a questionnaire survey, a conference and an article in a newsletter to communicate with a wide group of women.

The evidence gained from different methods indicates that patient involvement is both uncommon and controversial. All the exceptions were where patients had a voice at the decision-making stage, related to the health of women around child bearing. The next section considers whether patients are aware that they are receiving care in accordance with local or national standards.

7.5 Patient awareness and staff-patient communication

This section explores whether patients are aware that they are being treated in accordance with an agreed care standard, and if so, how staff use standardised care when communicating with patients. However, it is important to note that many factors influence patient preferences for information, participation in decision-making and choice. These include the severity of the illness, the nature of the procedures involved and their individual circumstances (Fotaki *et al* 2007). For example, Wilkinson *et al*

(2008) conducted a prospective, questionnaire-based study in an acute teaching hospital, finding that 66% patients wanted extensive information about their condition; whilst 61% of those responding to anther question, preferred to take a passive role in decision-making about their treatment. Duggan & Bates (2008) reporting the findings from structured interviews with 1,717 general medical patients, found that those with cardiovascular diagnoses expressed low desires for information. Fotaki *et al* (2007) identified three factors that limit patient choice: an attitude that the doctor knows best, lack of information about treatment options, and their beliefs, values and experiences.

7.5.1 Do patients know they are receiving standardised care?

Evidence from the opinion leader interviews provide a mixed picture of the extent to which working to standardised care is made explicit to the patient or carer.

Only two of the 13 opinion leaders who commented about patient awareness thought that patients were aware that they were receiving standardised care. A nurse manager gave an example about expert patients, saying that …

> *'people with chronic disease who are the expert patient … they are much more challenging and will question what is done.'*

A specific example was offered by the medical practitioner with direct experience. He illustrated the awareness of family members about the end of life care pathway by saying …

> *'Yeah very much so. Some of the patients are, but certainly the carers are. Early on we had a lovely letter from one family who wrote in and actually said that they felt the care their relative received was excellent, and that they felt that the care pathway ensured that they had got that.'*

However, four other opinion leaders did not think that patients were usually aware that their care was given in accordance with national or local standards. Three predicted an increase in awareness as a result of changing patient expectations and the availability of healthcare information on the Internet. Two nurses with direct experience said that they may allude to them when explaining their actions or decisions, but …

> *'I don't say that I am working to a protocol in those words.'*

A general practitioner, in the context of praising the standardised care embedded in the Quality and Outcomes Framework, observed that …

> *'I think actually that we have been poor at telling people why we do that. I think we think that everybody knows. But it is partly because we haven't got time to communicate it. Actually the government has been pretty poor. I think they're always so reactive about all the things they're being criticised about.'*

Four opinion leaders described how standardised care can facilitate the process of care. Using a document that sets out the standard of care was said to improve compliance and assist patients' understanding of the whole care process because …

> 'they can see what's expected to happen to them, it is all upfront in the care pathway.'

A practice development nurse suggested that …

> 'we are now getting really empowered patients, and I think care pathways are helping with that.'

One of the clearest ways in which standardised care is made explicit to the patient is through it's impact on staff-patient communications. This is considered in the next section because communication is one of the core features of quality of care.

7.5.2 Standardised care: tool for communication

Protocols, guidelines and pathways were said to be help communication by giving staff a structure to discuss benefits and risks, to help patients make choices and to give informed consent. Standardised care was reported to be useful in raising awareness about certain topics, such as the likelihood of pressure sores on discharge and when explaining why a request was being refused. This is illustrated by the following quotation from an opinion leader, a nurse with previous experience who said …

> 'We would allude to them, particularly in the termination of pregnancy clinic. For example, an older man (not the father) would bring in a young girl. There would be a story about why the mother shouldn't be involved. We would always say 'we have to refer her to social services because she is under 14, it is an unplanned pregnancy, her mother does not know about it and you are not the biological father. Our protocol states very clearly you cannot consent for her.'

However, a health service researcher drawing upon personal experience offered a different perspective, observing that …

> 'Nurses have always explained peoples' care to them and you don't have to have a protocol to do that. As a patient, I have never been shown a protocol that applies to my care. I've been told this will happen to you, and if this doesn't happen, then this will happen but if it does then this, but you know that would have happened anyway and that's not protocol-based care.'

Within the case studies, clearer evidence was found of standardised care being used as a communication tool. In particular, for raising sometimes sensitive topics, and for structuring conversations with patients and carers. The point about difficult topics is exemplified in the nursing case study about the Liverpool end of life care pathway (LCP). A medical practitioner illustrated how the pathway is used as a prompt and to ensure quality of care, by trying to …

'make death a positive experience for the patient, family and staff – that is what it is there for … you only have one chance to get it right …it's important to have guidance to help you do the best you possibly can. It provides a joined up approach for all the team who are caring for that person, prioritising what's important at the end of a person's life …. Looking at the patient and their family holistically – what care they need, their spiritual needs – those elements of care that it might be assumed that someone else has done it – a way of checking and making sure that everything is done … this might not happen, if there wasn't a document, a prompt that makes everyone say 'now we're shifting emphasis, this patient is actually dying, so we are all going to start singing from the same song sheet by using the same model of care … If the family know the patient is dying it helps them to understand the change in emphasis. The LCP prompts that … Hopefully, at the end of that; the family will receive quality care.'

The case studies provided evidence that standardised care influenced staff patient communication in other situations, and that patients knew that their care was following

a prescribed route or that they were receiving the same care as everyone else. One of the best examples came from the nursing case study about the myocardial infarction care pathway. A nurse described how she used a patient version of the pathway, using it to structure conversations with the patient and their relatives, before asking them to sign it, to indicate their consent and then filed the form in their notes. She commented that the summary was liked by both patients and relatives …

'because they can see what is going to happen on a day-to-day basis: what tests will be done; and they can see that they are getting better, when by day five they are doing more for themselves and getting more mobile … it gives relatives an insight into what is going to happen so they are not left in the dark. That's the feedback that I've had. I've never had any patients who complain about it. …. They are usually upset and apprehensive because of the diagnosis but when you go through it, it seems to relive a lot of anxieties.'

Practicing health visitors at both case study sites spoke about how the protocol/pathway for maternal mental health allowed them to raise the topics of anxiety and depression with all women. Many spoke about the benefit of "*normalising depression*" and reducing the stigma of mental health. The pathway/protocol seemed to legitimise talking about difficulties with coping or bonding with their baby. Some health visitors described how some new mothers would ask about it, because the assessment was "*talked about on the grape vine*" and how women, with their second or third baby would ask jokingly about the mood assessment. Several health visitors emphasised equity - with all mothers being treated the same as part of a universal service - and also that mothers understood that …

'health visitors are there for them and not just to carry out developmental checks on the baby.'

A further example was given by a community midwife with more than twenty years experience. She described her role interpreting hospital guidelines for women, their partner and families …

> 'If a woman was coming up to being two weeks overdue, then I would sit down, talk to her about the hospital's guidelines, saying "they'd rather you didn't go more than two weeks overdue and what they suggest will happen if you go there is … and how does that feel to you?" We'd talk about the guidelines and if the woman had any particular anxieties about them, then we'd try and explore them a bit or I'd have a word with the doctors. So, it was actually using them with her.'

These examples of nurses, midwives and health visitors using standardised care as a communication tool, indicate the value of these documents explicitly supporting practice. Clarity of communication and understanding is likely to contribute to high quality patient care.

7.6 Impact on patient outcomes and experiences

A key question about standardised care is – if staff use a protocol, guideline, pathway or other form of standardised care, does this improve patient experiences and outcomes? The aim in this research was more specific – to understand how the contribution of nurses, midwives and health visitors to standardised care impacted on patient experience. This section draws on proxy, anecdotal data about the perspective of nurses, midwives and health visitors, their views about the impact of standardised care on patient outcomes, as well research findings.

7.6.1 Evidence of impact on patient outcomes

Measuring the impact of standardised care on patient outcomes has been approached in many ways and the outcome measures used are contested tools. In July 2002, Bandolier examined the evidence from seven randomised trials about the effectiveness of treatment protocols (which included clinical pathways, care paths and critical pathways). The outcome measure in most studies was length of hospital stay and they report a general consistency in delivering better care, or lower costs or both (2002: p10). Van Herck, Vanhaecht & Sermeus (2004) tested a broader way of categorising the effect of clinical pathways using five distinct domains, each with measurable indicators. The domains were:

1. clinical indicators, (number of re-admissions; number of complications; mortality; number of admissions or length of stay on the care pathway; number of prevented admissions; and relapse without re-admission);

2. service indicators (patient satisfaction);

3. team indicators;

4. process indicators; and

5. financial indicators.

Their literature review of 200 abstracts/papers published between 2000 and 2002 indicated that clinical effects (see 1.) were reported most frequently, in 65.5% of papers, and that the service indicators i.e. patient satisfaction, was reported least frequently, in 18.5% papers (Van Herck, Vanhaecht & Sermeus, 2004).

Other studies have investigated the impact of standardised care on the patient outcomes, producing equivocal findings. For example, a realist synthesis of the literature found variable patient outcomes (Rycroft-Malone *et al* 2007); and Graham *et al* (2003) found that only 5% of guidelines had been evaluated to determine their impact on health outcomes. A more recent critical review of care pathway evaluation research (El Baz *et al* 2007) used three clinical outcomes (length of stay, readmission rate and complications) and one organisational outcome (costs). Of the 115 papers appraised by El Baz *et al* (2007), 67% were classified as low quality. They concluded with a warning …

> *'that readers must be extremely cautious when interpreting the results of clinical pathway evaluation studies because of the confounding factors and sources of contamination affecting the internal and external validity of most of the published studies.'* (p6).

The equivocal evidence about the impact of standardised care on patient outcomes is both surprising and disturbing, considering the prevalence of this way of working. Considering the paucity of evidence, it is not surprising that the research found little practitioner knowledge about outcomes. The case studies provided some anecdotal evidence about the impact of standardised care on patients but more often, the question about impact resulted in a general comment, such as this made by an operational lead …

> *'It is difficult to assess the impact of guidelines on care … in theory they should (reduce risk) but I don't think there has been any good studies to look at this.'*

Many participants expressed an interest in patient outcomes whilst acknowledging that this was difficult to obtain, whether from audits or research. Audits tended to concentrate on the process of care, particularly staff compliance, rather than the patient experience, a finding also apparent in the development/implementation systematic literature review reported in chapter four and appendix 2. The next section explores perception of the impact of standardised care on the patient experience of care.

7.6.2 Patient experience: benefits and drawbacks

An important quality dimension is whether standardised care improves the patient's experience of care. This section draws upon findings from the survey, opinion leader interviews and case studies to review the perceptions of nurses, midwives and health visitors about the benefits and drawbacks of standardised care for patients.

A question on the survey probed the beliefs of these staff groups about standardised care. Four items related to patient care and the scale was derived from the Modernisation Agency guidance which identified the benefits of protocol-based care (MA/NICE 2002). Further details about survey and questionnaire are in appendix 3. The survey results are given in Table 8.7 which show that over two thirds of respondents agreed with the statements that standardised care supported safe treatment and effective interventions, provided clarity about care standards and reduces variation in the quality of care.

Table 7.7. Perceptions about the impact of standardised care

	Agree/ strongly agree %	Neither agree or disagree %	Disagree/ strongly disagree %
Promotes safe treatment	71.1	15	13.3
Reduces variation in the quality of care	75.8	9.4	14.8
Provides clarity regarding care standards	77.1	10.3	12.6
Supports effective interventions	66.5	19.6	13.8

N=2,711

The opinion leaders were invited to report any evidence, whether from research studies or from their experience, about the impact of standardised care on patient experience. All of those (13/35) who responded drew upon their personal experience, usually giving examples of the positive impacts and drawbacks for both services and patients.

Positive impact on patient services: Many of the perceived benefits related to the quality and co-ordination of care between professionals and across health and social care. The quotation, from a nurse in a joint practice/academic post, encapsulates the range of perceived outcomes for patients, staff and organisations expressed by several opinion leaders …

> *'Reduces variation in terms of getting rid of that off the wall decision-making. It promotes multi-professional working. Clarity about who does what. Supports the provision of adequate education and training, if it works. And promotes working across health care settings. So if all the aims are met, then they are the benefits really. But the big thing is about quality of care, ultimately. I suppose everything that we have mentioned around accessibility and quality and risk.'*

Specific examples of improved patient care were given by four opinion leaders, all with direct experience. A practice development nurse described the reduction in the length of hospital stay by one day for hysterectomy patients, following the introduction of a care pathway. A medical practitioner talked about the confidence of families caring for people dying at home because …

'they will have the documentation and they then have expectations of the care … and we found that quite empowering for families … before they go to the doctor they will have looked through and will have seen what the guidelines are.'

Another medical practitioner reported how a midwife had identified a problem with young mothers with substance misuse and had established a new service targeted at their needs. The fourth example was given by a health visitor who described the support mechanisms and information resources that had been developed as spin off benefits from a care pathway, saying that …

'we've been able to put a huge amount in for women.'

Patient benefits were most frequently reported in the provision of new services at the case study sites. This was because the standardised care had highlighted gaps in services needed to implement the standardised care. New services and new patient information leaflets were a feature of both health visitor case studies. The maternal mental health pathway and protocol highlighted gaps in service provision - whether for listening visiting or mental health support groups – that were addressed. For example, a mental health worker described collaborating with health visitors on designing and co-facilitating a short, intensive course to teach self-help skills to mothers with mild to moderate depression. She added that …

'patients benefit from a more joined up service … patients like the idea that you know their health visitor and that you can have a discussion with them if needed. The same applies to the GPs and the wider primary care team: we know them and can easily have a conversation with them.'

Drawbacks for patients: No examples of negative patient outcomes were reported by the five case study sites, primarily because the nurses, midwives and health visitors said they used standardised care flexibly, adapting and applying the standard to the needs and circumstances of individual patients. This may also be due the participants' investment in 'their' standardised care.

However, eight opinion leaders (three nurses, two health service researchers, two medical practitioners and one policy maker) identified a number of drawbacks of standardised care for patients. They were:

- **Less choice**: A reduction in choice was mentioned by a practice development nurse, a medical practitioner, a health service researcher and an opinion leader with a legal background. Less choice was associated with cost cutting, the expectation of staff compliance, and because it …

  'does not leave the professional or the patient space to negotiate and say "well this isn't acceptable to me but this is too little, can we compromise in the middle?" So I think that can be a disadvantage' (health service researcher).

- **Less informed consent:** Four opinion leaders (a midwife, a health service researcher, a medical practitioner and a law lecturer) were concerned about the implications for informed consent. This was raised in the context of giving only the options set out in guidelines, rather than all the possible options …

  'I suppose there is an issue of informed consent. When you're talking about patient's treatment and you deliberately don't mention certain things because there are guidelines on it. Is that legitimate? … You're only giving them half the story, because you can give them only half the treatment.'

- **Less individualised care:** A nurse researcher and medical practitioner, both with direct experience, mentioned less individualised patient care because …

  'not every patient fits a protocol'

  and also …

  'if they are imposed rigidly then the patient's individual circumstances will not be taken into account … sometimes we can end up riding roughshod over patient's wishes … the guidelines can end up forcing us into being more narrow-minded in our approach and simply say "well you've got to come into hospital or you've got to sign a discharge form" whereas, more individualised patient-centred care would say, "well actually if we can set up a few services to help you, and if you're prepared to accept the risks associated with this, then you can go home".'

Other aspects of the loss of individual care were expressed by two nurses, a policy maker and another medical practitioner. Firstly, there may be good reasons for variation, which was expressed by a medical practitioner with direct experience …

  'certainly as clinicians, first of all there are often clinical reasons why an individualised form of care might be better than protocol-driven care.'

A policy maker and a nurse researcher in a joint academic/practice post reinforced the point that "*some patients don't actually fit protocols.*"

- **Fragmented care:** A nurse in a policy making role reflected on the impact of '*blinkered*' thinking on continuity of patient care, saying that standardised care …

  'can hinder that team approach, because people get so caught up in "it's what's in the protocol." You know, that kind of very blinkered "I have no autonomy as a practitioner, I can only do what the protocol allows me to do and then it becomes somebody else's responsibility or whatever." It can make care feel very fragmented and episodic from a patient's perspective because I don't look at your holistic needs. I look at the task element of the protocol that I am responsible for delivering.'

This section explored the range of perceived benefits and drawbacks of standardised care for patients and carers. Although the evidence was proxy and anecdotal there were some consistent themes across the survey, opinion leader interviews and case studies; with the benefits relating to new services and drawbacks highlighting concerns about less individualised care.

7.6.3 Summary of impact on patient experience and outcomes

Although health and social care policy, and the specific guidance for protocol-based care, promote patient involvement to inform personalised care, there was little evidence of patients contributing to the development, implementation or review of standardised care.

Where evidence existed, it related almost exclusively to the development of standardised care related to women and their ante and post natal health.

It is clear that the benefits of involving patients in developing standardised care are not universally agreed upon. Some informants questioned whether it was feasible to expect patients to contribute to development of tools designed to help staff with clinical care processes.

Most participants reported alluding to standardised care, rather than explaining to patients that they were giving care in accordance with agreed, evidence-based standards. Staff-patient communications provided the clearest evidence of the way standardised care could affect patient experience. Standardised care was a tool that gave structure and was a prompt for staff-patient communication, especially about difficult topics, such as end of life care; and also for de-stigmatising topics such as partner abuse, which were asked of all women as part of the maternal mental health protocol/pathway.

There was little research, audit or experiential evidence about improved patient outcomes. Most informants concentrated on the process, rather than the outcome of standardised care. As a result there was also little knowledge amongst practitioners about the impact of involving patients in the development process. New services, such as support groups and information leaflets developed to implement the standardised care, were the most frequently mentioned patient benefit.

7.7 Summary

The third research aim proved the most challenging of all. This was largely due to the lack of evidence about the unique effects of nurses', midwives' and health visitors' contributions to standardised care on the specified outcomes.

This chapter draws together proxy evidence about patient experience and outcomes, and approximate evidence about costs to try and shed light on the key issues and highlight areas for further research. The paucity of economic evidence about costs is concerning,

considering the drive for efficiency in the NHS. The lack of patient voice is also surprising given that patient involvement was one of the steps recommended in the guidance about developing protocol-based care (MA/NICE 2002) and is promoted in policy. When standardised care is used as a tool for staff-patient communication; and when it highlights gaps in service provision, it does seem to contribute to the quality of patient care. However, perhaps most concerning is the apparent scant evidence that standardised care improves patient outcomes. The implications of these findings are discussed in the final chapter.

8 Conclusions: Getting the balance right

This report and the annexes present findings from a major, mixed method programme of research about the involvement of nurses, midwives and health visitors in the development of standardised care and the impact that this way of working has upon their professional lives. Specifically, the research set out to achieve the following aims:

1. Identify the range of settings into which different models of protocol-based care have been introduced.

2. Examine the ways that nurses, midwives and health visitors contribute to protocol-based care (development, implementation, audit and review).

3. Identify the impact of their contribution on organisational, patient, staff outcomes, costs and quality of care.

4. Assess the overall impact of the introduction of protocol-based care upon the work of nurses, midwives and health visitors and their sense of professional identity and capacity.

A range of methods were used to explore the meanings, experience and impact of standardised care from the perspective of nurses, midwives and health visitors. The methods were interviews with 35 opinion leaders, a three-part systematic literature review, a national survey and five case studies. The research included an economic analysis of the cost of developing, implementing and monitoring standardised care. Details of the research methodologies and summary findings can be found in the appendices.

The mixed methodology allowed these research aims to be explored iteratively, from multiple perspectives and drawing upon different sources of knowledge. For example, the national survey examined the meaning and status of standardised care because the opinion leader interviews had highlighted confusion about terminology. The systematic literature reviews revealed gaps in knowledge about the cost of development and about the sustainability of standardised care, aspects that were followed up in the case studies. Perspectives on standardised care were sought from practitioners, policy makers and researchers in the opinion leader interviews; and from strategic managers and front-line practitioners at the case study sites. Both the development/implementation systematic literature review and the case studies drew upon the everyday experience and tacit knowledge of practitioners (Pawson *et al* 2003) which complemented the knowledge in policy documents that provided the context for the research.

Each method within the research has its limitations. The opinion leader interviews with a small, purposive sample of people from practice, policy and research backgrounds gave a snapshot of views at one period in time (2004-2005). Standard systematic literature review methods, using multiple search terms and search strategies, produced few

relevant, high quality studies published in English that addressed either the costs or impact of standardised care on nurses, midwives or health visitors. The national survey, although constituting a large sample, had a low overall response rate (21 per cent). Distribution problems with the CPHVA sample meant that the response for health visitors was disappointing (five per cent) compared with the response rate for nurses and midwives (31 per cent). The survey population characteristics however are representative of NMC registrants (2007). The reader is asked to take note of the strengths and limitations of the methods when reviewing the summary findings and implications for policy, practice, education and research.

In chapter eight:

Section 8.1 clarifies definition and sets the policy context for the research.

Section 8.2 summarises key findings in relation to each of the research aims.

Section 8.3 discusses these findings with reference to the wider organisational literature and draws together recommendations for policy, practice and the professions.

Sections 8.4 and 8.5 look at future trends in the NHS and challenges to standardised care.

8.1 Policy context for this research

Protocol-based care was launched in The NHS Plan (DH 2000) and is an umbrella term for documents that influence and direct clinical care processes. Documents such as are pathways, clinical guidelines and care bundles set standards and standardise care with the aim of reducing unacceptable variations and improving safety through the introduction of evidence-based care.

Although protocol-based care is the term used in policy documents, it was rarely used by the opinion leaders interviewed at the first stage of this research. In fact, there was lack of clarity about the meanings of a variety of terms used to formalise care processes. Throughout this report, therefore, standardised care is used to collectively describe protocol-based care, clinical guidelines, care pathways, algorithms, flowcharts, care bundles and other documents aimed at codifying care practices.

Policy documents and those responsible for producing national clinical guidelines continue to emphasize the need to preserve clinical autonomy, stating that standardised care should support, not replace clinical judgement. However, the emergence of this way of working has generated debate about whether standardised care achieves its stated objectives, and if so, at what cost, to other aspects of health care. For example, Woolf *et al* (1999) suggest that clinical guidelines are useful where appropriate practice is unclear and scientific evidence can provide an answer, but otherwise offer a poor remedy; and Carryer *et al* (2007) writing about nurse practitioners, draws a clear distinction between guidelines that aim to support practice, and protocols which aim to control practice.

It is also important to note shifts in the policy context since the research started in 2004. Some of the original drivers of standardised care remain strong, such as quality

of care, clinical governance and patient safety, especially for service commissioners. Other drivers are being reframed. The challenges of evidence-based practice are being re-examined as implementation science, to identify the best ways to overcome the gap between translating research knowledge into practice. Interestingly, the driver of standardisation to reduce unacceptable variations in practice and patient outcomes seems to be less prominent, with a move towards locally-led, rather than nationally prescribed services and standards. Lord Darzi's review of the future of the NHS in England is proposing that health organisations will be responsive to, and lead by the local community in that …

> *'all change will be locally-led. Meeting the challenge of being a universal service means the NHS must meet the different needs of everyone. Universal is not the same as uniform. Different places have different and changing needs – and local needs are best met by local solutions'* (Darzi 2008 p12).

The emphasis on quality and safety remain high, and the debates about the benefits and costs of standardised care remain as relevant as ever in today's NHS, especially in the context of commissioning and personalised health and social care.

8.2 Key findings in relation to each research aim

The key findings about each of the four research aims are summarised in the next section. The appendices contain full details about the methodology and some results for each method.

8.2.1 Settings where standardised care is used

First and foremost, the findings suggest that, as anticipated in The NHS Plan (2000) standardised care is widespread throughout the NHS in England. The data from the first national survey (N=2,711) indicates that nurses, midwives and health visitors use standardised care across primary and secondary care, in different specialities and for a range of activities.   Over 90 per cent of respondents had used standardised care in their practice *'to a moderate or great extent'* in the last two years; and two thirds used guidelines and protocols for *'most or all'* of their direct patient care.

The proliferation of standardised care in the NHS masks a great deal of variation in both its purpose and understanding about its status, meaning the degree of compliance required. There was general agreement about the most appropriate tasks and settings for standardisation: those considered most amenable were predictable, routine tasks, where the evidence is incontrovertible; and in rare or high risk situations. Standardised care was also viewed as offering role and procedural clarity for new practitioners; and supporting extended roles and specialist practice. There was debate about the degree of

compliance standardised care should, or can command, especially in health care situations that are often characterised by complexity and uncertainty, requiring a higher degree of latitude so staff can use their knowledge, experience and judgement to deliver the most appropriate care.

8.2.2 Contribution of nurses, midwives and health visitors

Findings from the survey show that nurses, midwives and health visitors are integral to all stages, from initiation through development, implementation, audit and review. Standardised care is an organisational change, often initiated by nurses, midwives or health visitors in response to a specific need or incident, and driven by specific expertise and passion for improving patient care or service transformation, such as evidenced-based guidelines that underpin midwifery-led care. It can also be a macro level, policy driven change or a micro level change that involves formalising current practice. In all cases, their role as champions, leaders and brokers, is important for both adoption and sustainability.

Guidance documents identify a number of roles and activities in the process of developing standardised care (MA/NICE 2002, MA 2005). Evidence from the literature review and case studies suggests that in reality, these processes are more complex and protracted, and as a result, the roles can be resource intensive for nurses, midwives and health visitors.

These staff groups often play a key role in negotiating with medical and other professional colleagues for the adoption of standardised care within the multi-disciplinary team and across clinical specialties. One challenge they face in this brokerage role is overcoming or accommodating cultural differences between the professions, (particularly between doctors and nurses). This can result in resistance, different approaches to, and less use of standardised care, that to some degree can be attributed to the general suspicion about the deleterious impact of standardised care on professional judgement and autonomy. These findings highlight the importance of gaining commitment, especially from medical practitioners, if standardised care is to succeed in a multi-disciplinary setting.

Ilott *et al* (2006) used concept analysis to identify two archetypal settings where standardised care is used, with implications for its acceptance. Their findings suggest that the introduction of standardised care may be easier in specialist settings where staff may be more motivated to take on roles that expand their scope of practice within a speciality. Conversely, in generic situations where staff are expected to incorporate a form of standardised care within their everyday practice (e.g. guidelines for mouth care in an acute setting) there may be more resistance to change, particularly where it is perceived as imposed or where there is a lack of shared meaning across professional groups about the standardised care.

8.2.3 Impact on staff, patients, organisations, costs & quality of care

Given the prominence of both cost effectiveness and individualised patient care on the policy agenda, it was perhaps surprising to find little evidence, not only on the impact of specific contributions from nurses, midwives and health visitors, but more generally on the impact of standardised care on organisational, patient and staff outcomes, costs and quality of care.

No research was found that directly compared outcomes of standardised care dependent on who contributed to it, however given the prominence of the nursing, midwifery and health visiting roles in the development process, some tentative conclusions can be drawn from the findings of this report in relation to some of these outcomes.

One of the key purposes of standardised care is to improve patient outcomes by reducing unacceptable variations in care. The majority of survey respondents believed that standardised care achieved this purpose, as well as improving safety and quality of care. However, this belief is not yet supported by the evidence, with recent literature reviews producing variable findings about whether standardised care improves health outcomes (El Baz *et al* 2007; Rycroft-Malone *et al* 2007).

Standardised care was reported to influence the patient experience when it was used as a communication tool, giving staff a structure to explain the care plan and permission to broach sensitive subjects, such as end of life care.   Another positive impact was the development of new services to meet gaps in provision identified by the standardised care.

There were relatively few examples of patient involvement in the development of standardised care, and the feasibility of patients contributing to clinical care process was questioned, suggesting that nurse, midwife and health visitor input into standardised care is not always associated with an increase in patient involvement.

With regard to organisational outcomes, standardised care is an innovation in the workplace. Standardised care involves organisational change in that it introduces new clinical care processes, new ways of working, new nurse-led services and extends the scope of practice in midwifery and health visiting, for example. Viewed from a change management perspective, one of the main impacts of the contribution of nurses, midwives and health visitors specifically, is facilitating the change process. Involving these staff groups, who comprise the majority of the NHS workforce, in all stages of standardised care, is likely to enhance understanding, ownership, acceptance and adoption of the proposed change.

There is a notable knowledge gap with regard to the costs of standardised care. The economics literature review revealed little evidence about the whole area in general, and to nurses', midwives' and health visitors' contributions in particular. There is negligible information about the cost of adapting national guidance to local use, and about the cost of complex standardised care involving multiple treatment decisions and different professions.

The economic case study data represents a '*best guess*' about resource costs, derived from retrospective, variable documentary evidence available at each case study site and

the recall of the operational lead. The average, estimated cost for each standardised care was £139,000 over five to eight years, across the three case studies. Most cost was incurred when rolling-out an existing pathway within a district general hospital, with the first two years costing approximately £117,000. Although this is the first time the costs for development, implementation and monitoring standardised care have been quantified, they are likely to be an underestimate of true costs.

8.2.4 Overall impact on professional identity and capacity

A range of positive and negative impacts on professional identity and capacity were identified consistently across each method. Standardised care was perceived to have a positive outcome when it offered role and procedural clarity; giving a sense of security and confidence from using evidence-based guidance; and when it was used with discretion, to support rather than replace their professional judgement. This enabled nurses', midwives' and health visitors' to act autonomously, believing that they were better able to respond to patient need, and so improve quality of care. There was a consensus that standardised care was particularly useful for new, inexperienced and locum staff who may not yet have accrued the knowledge to enable them to be effective or confident in an unfamiliar setting. The evidence-based standards also gave these staff groups a '*voice*' when challenging medical practitioners about patient care, especially about compliance with the standardised care.

A second positive impact was that of increasing professional autonomy through expanded roles and specialist practice. This was associated with the modernisation of health care practice and workforce redesign, with new services, skills mix and nurses particularly, taking on tasks and roles traditionally performed by medical practitioners.

However, this positive impact was sometimes contested by participants who were concerned about the implications for decision-making and autonomy. A consistent concern, raised in each method by a range of participants, was the risks of becoming rule-bound, of following standardised care '*slavishly*' and 'without thinking' or assessing whether it was appropriate for an individual patient. Some participants questioned the balance between autonomy and accountability, with standardised care being perceived as controlling practice and constraining the art of nursing, which means …

> '*sensitively adapting care to the needs of individual patients, and in the face of uncertainty, the discretionary use of creativity*' (Finfgeld-Connett, 2008:p387).

Some of these concerns reflect the ambiguous status and meaning of the different forms of standardised care. For example, four fifths of survey respondents indicated that they understood '*protocols*' to mean specific, mandatory procedures that require compliance; whereas the status of guidelines was perceived to be advisory, offering '*guidance.*'

The impact of standardised care on important staff outcomes such as autonomy and well-being was tested in the national survey. Standardised care can be seen as the formalisation of work processes because it involves formal, written instructions about care processes that specify '*who should do what, when and how.*' Adler & Borys (1996)

suggest that formalisation can be enabling or coercive, depending upon how the 'rules' are perceived and operationalised within an organisation. The survey tested whether three enabling features – involvement, transparency and flexibility – had an impact on staff. These enabling features showed significant associations with a range of staff outcomes, namely:

- Flexibility of use: Discretion to vary from standardised care was the strongest predictor of higher levels of professional autonomy and perceptions of better/individualised patient care.

- Involvement in development and improvement: Involvement was the strongest predictor of job satisfaction, enthusiasm and contentment. It was also a significant predictor of skills use.

- Transparency: Understanding 'what to do and why' was the strongest predictor of role clarity and self-efficacy (confidence in one's capability to carry out work tasks).

Ideological fit was also important, showing a positive relationship with well-being, suggesting that when staff perceive that standardised care supports their ideals of good patient care, such as giving quality and timely care, they report higher levels of psychological well-being.

The evidence about the impact of standardised care on team working was more mixed. Supporting effective multi-disciplinary team working is often cited in policy documents as a benefit of standardised care. Opinion leaders and survey respondents were split on this point and evidence from the case studies provided both positive and negative examples. The main difficulties appear to arise when standardised care is viewed as purely '*nursing documents*' that do not apply equally to medical practitioners. In some cases there was the suggestion that different attitudes within the team toward standardised care could lead to friction, variation in practice and low take-up of the standardised care. There was however evidence from a few interviews and case studies that attitudes were changing, especially amongst junior doctors, who valued the procedural guidance given in the standardised care.

The impact of standardised care on nurses', midwives' and health visitors' knowledge and skills is another important theme. Only two in five survey respondents agreed with the statement that standardised care made best use of their skills and knowledge. This exposes one of the inherent tensions around the introduction of standardised care: many nurses, midwives and health visitors agree that it is consistent with increased quality, safety and consistency of care, but at the same time are more reserved about whether it makes full use of their abilities and skills.

8.3 Discussion and recommendations

Lord Darzi's Next Stage Review which is developing a vision for the health service over the next decade, appears to herald a shift from a top-down approach to a locally-led

NHS. However, quality improvement remains important, with one of the Review task groups charged with developing a strategy for …

> 'speeding and embedding quality improvement across the health and social care delivery system, to included drawing on international evidence of best practice in standard setting, data collection in practice, inspection and review of health care services and supporting quality improvements' (King's Fund, 2008 p5).

This statement, which echoes the quality agenda articulated a decade ago in 'A First Class Service. Quality in the new NHS' (DH 1998), suggests that standardised care, as a way of 'standard setting' is as important as ever. The findings from this research are therefore timely, providing as they do information about the costs and 'enabling' characteristics of standardisation.

The following recommendations are deliberately board and wide ranging, for two reasons: firstly, to reflect the diversity of standardised care as a concept and tool for evidence-based nursing, midwifery and health visiting; and secondly, to offer flexibility in the context of the forthcoming Darzi Review of the NHS in England.

8.3.1 Developing 'good' rules

Standardised care can be seen as the formalisation of work practices as it involves written rules and instructions that specify 'who should do what, when and how' in delivering patient care. Extensive organisational research has shown that formalisation can have positive and negative effects on employees. In the former case, rules and procedures can provide support and guidance, clarify responsibilities, make individuals be and feel more effective, and consequently enhance satisfaction and well-being. In the latter case, formalisation can stifle innovation, restrict individual autonomy and, increase feelings of workplace alienation and reduce well-being. Adler and Borys' (1996) conceptualisation of enabling and coercive formalisation, examined in this research, offers a way of bringing together these two perspectives about 'good' and 'bad' rules. The framework, and our findings suggest that either can hold true, depending on the way that standardised care is developed and implemented.

The positive relationship between three enabling features of standardised care (involvement, flexibility and transparency) and positive staff outcomes such as autonomy and well-being, are important, indicating that they should be incorporated into future standardised care. These features counter professional concerns about coercive rules that control practice, restrict ability to give personalised care and lead to unthinking compliance that could compromise patient safety. The enabling features and ideological fit may also affect other processes and outcomes, such as change management and staff turnover. However, any such recommendation needs to be balanced with the associated costs, and the implications for nationally developed standards, such as NICE clinical guidelines.

Policy recommendations:

1. Within policy documents on standardised care, more emphasis should be placed on the methods and procedures for developing standardised care, particularly

involvement, flexibility and transparency as these are associated with beneficial staff outcomes.

2. Consideration should be given to training or education programmes to reinforce understanding of formalisation, including the impact of different types of rules on behaviour.

Practice recommendation:

1. Those leading the development and implementation of standardised care at a local level are often best placed to ensure that work is conducted in line with the enabling aspects of formalisation, so optimising the impact on end-users. Recommendations for those leading and supporting practice development at a local level include:

   ▪ **Involvement**: Communication and consultation strategies at the local level to ensure the direct and indirect involvement of end-users in the development and implementation of standardised care. Additionally local mechanisms should be established with the introduction of a standardised care procedure to enable staff to assess, review and contribute to the improvement of the procedure.

   ▪ **Transparency**: User-friendly, well-written documentation that clearly states '*what to do and why*' and specifies '*who, when, where and how*' (Mitchie & Johnston 2001). Transparency includes consideration of the local context for the standardised care and needs to feature in induction and on-going training to ensure that staff understand the precise nature of the tasks they are required to perform and the underpinning rationale/evidence-base.

   ▪ **Flexibility**: Training and documentation should emphasize the importance of discretion and professional judgement when using standardised care, unless compliance is deemed critical for patient safety.

Research recommendation:

Longitudinal and change studies should be conducted to identify the cause and effect linkages between enabling features (transparency, flexibility and involvement) and positive staff outcomes. This would allow the framework to be tested more fully and in different clinical settings.

8.3.2 Standardised care: managing change

Although standardised care may be policy driven or locally owned innovation, requiring a change in practice, or just a way of formalising current practice, the research revealed that little attention is paid to the complexity of organisational change in the NHS and the management of change (Illes & Sutherland, 2001; Greenhalgh *et al* 2004).

One subtle aspect is the meaning of the change, which can be pivotal to acceptance and adoption. The meaning that standardised care procedures hold for staff has a strong influence upon their motivation to use them. Reframing the meaning might need to occur within teams, so that there is a shared belief that standardised care supports individualised care, for example, to prevent resistance and disharmony, which may then

jeopardise adoption. This reframing can be powerfully influenced at a local level, by consultants and ward managers, who can be effective role models, helping drive the successful adoption of standardised care. Medical consultants and ward managers have a particular influence on the beliefs and actions of the team. Showing indifference towards the protocol or guideline can be sufficient to inhibit its use. The importance of changing hearts and well as minds was also noted by Claridge *et al* (2006) about the introduction of integrated care pathways.

The case studies also illustrate the need, not just for proactive, passionate champions with professional credibility able to lead the change, but also continuity of involvement to sustain the momentum as the standardised care is developed, used, audited and reviewed over five to ten years.

The research highlighted the importance of strategic level commitment, support and resources for standardised care. We found instances where organisational priorities changed resulting in the abandonment of standardised care after several years of development, piloting and auditing. The costs of such 'failures' are also hidden, and extended beyond money, to disappointment amongst the workforce, and in some instances, to the operational lead being made redundant from a practice development post.

Policy recommendation:

There is a need to incorporate change management into education and training, and also to ensure clarity of purpose, meaning and status of standardised care and about how these documents should be used.

Practice recommendations:

1. Assessment of whether or not to introduce standardised care needs careful consideration of the existing culture or attitudes at a local level. Understanding reasons for resistance or fears, especially about flexibility of use, reduces the risk of the document being seen as 'coercive' and enhances psychological 'buy-in' from staff.

2. Operational and strategic managers, given the complexity of change, need to take account of the requirement of longer-term commitment for success, and also the resource and support needs of those leading standardised care developments.

8.3.3 Promoting clinical judgement and autonomy

Clinical judgement is a central theme in the discourse around the impact of standardised care. The potential impact on professional autonomy should not be taken lightly. There is strong and consistent evidence in the wider organisational psychology literature that autonomy impacts on employee well-being, attitudes, and behaviours (Humphry, Nahrgang & Morgeson, 2007). Studies across many contexts have established that enhanced employee autonomy and decision-making authority promotes better mental health and increased job satisfaction among employees. The research evidence on employee autonomy also points towards performance gains. Studies have shown that increased autonomy can improve employee motivation, can enable a quick response to

problems, and can promote the acquisition and use of knowledge, or 'working smarter', and lead to a greater propensity for employees to use initiative or to be proactive. Clearly these findings resonate with concerns expressed by participants in this study, and in the health care literature in general, about the potential impact of prescriptive care on employee morale, learning and development, and innovation. These concerns should not be taken lightly.

In the survey, discretion was associated with higher levels of autonomy, a factor consistently associated with job satisfaction, well-being and other important work outcomes; and also with perceptions of giving more timely, quality and individualised care, which is at the heart of nursing, midwifery and health visiting. The ability to use standardised care with discretion, as a tool rather than a rule, was viewed as core for acceptance and safe practice, both in the immediate and longer term. Exercising clinical judgement is vital to ensure that the standardised care is appropriate for each person and to avoid the risks of unthinking compliance. However, the prevalence of standardised care does raise questions about the impact of bureaucratic decision-making, in the specific sense of following institutional rules or guidelines (Porter *et al* 2007). If this has become the dominant mode of decision-making for these staff groups, then there is a need to reflect on the implications for developing problem solving skills, experiential learning and the progression from novice to expert practitioner. Other research suggests that flexibility in applying rules is critical for problem solving and increased learning (Parker & Wall, 1998). The situation may be further compounded by the lack of clarity about the status and meaning of the standardised care. There are a number of recommendations for practice and the professions arising from these findings.

Practice recommendations:

1. The purpose and status of the standardised care needs to be made explicit at the local level, especially whether it is mandatory or advisory. The conceptual confusion surrounding the exact implications of different forms of standardised care mean that status in a given setting cannot be assumed.

2. Acknowledge the need for, and limits of, clinical judgement in documentation and training. Recognise that this will vary dependent on the purpose of the standardised care and the specific setting in which it is operating.

3. Emphasize the learning, rather than the surveillance aspects of standardised care as a quality improvement initiative (Cooke 2005). This means using the 'repair' or learning opportunities from variations, variance tracking and audit, rather than as exceptions that have to be justified, especially as feedback and audit can have some effect on professional practice (Jamtvedt *et al* 2006).

Recommendations for the professions:

1. The professions should consider the implications of the apparent dominance of bureaucratic decision-making on practice (for autonomy, accountability, partnership working and patient choice) and also for pre and post registration education programmes.

2. Educators and practice development staff should review the consequences for the transition from novice to expert practitioner, as well as the future development of professional knowledge and skills.

Research recommendation:

Longitudinal studies are required to investigate the inter-play between standardised care, its flexible use, knowledge acquisition and use, and decision-making.

8.3.4 Identifying the costs of standardised care

There is scant evidence about the resource costs of developing, implementing and monitoring any form of standardised care. Findings from the case studies indicate that the development process is both costly and drawn out. However, these findings are based on *'best guess'* approximations and probably underestimate the true costs incurred. Additionally, no attempt has been made to calculate the costs of '*bad'* rules (in terms of reduced well-being and lower self-efficacy). Adopting the approaches recommended here in terms of '*good'* rules would clearly have significant cost implications, and so the balance of costs and benefits need to be appraised. Considering the proliferation of standardised care, urgent attention needs to be given to applied research into the costs of standardised care, both for locally developed innovations and when adapting national guidance for local implementation.

Policy recommendation:

1. To assess what data is, or could be, routinely collected to aid understanding of the costs of developing, implementing and sustaining standardised care, particularly the cost burden borne by trusts when tailoring and implementing national guidelines.

2. To ensure that the costs of development and implementation are included in any evaluation of standardised care as the results may have a profound effect on the policy conclusions.

Practice recommendation:

1. Managers and practitioners need to take account of the likely resource commitments involved in standardised care.

2. At a local level there should be appropriate planning and resource costing to support the implementation and development of standardised care. In particular this should help to inform decisions about whether developing standardised care is a feasible or appropriate response in a given setting.

Research recommendation:

Accurate information about the real costs of developing, adopting and sustaining standardised care is required. A framework for doing this is proposed which takes into

consideration the complexity of the standardised care, cost effectiveness and an evaluation of treatment consequences (see appendix 7).

8.3.5 Establishing the impact on patient outcomes

This research sought evidence on the extent to which the involvement of nurses, midwives and health visitors in the development of standardised care had an impact on patient outcomes. No evidence was identified which could address this point (ie that compared the impact of standardised care with and without nurses, midwives and health visitors input). Evidence from the survey suggested that nurses, midwives and health visitors are widely involved in the development of standardised care. The research found no evidence of standardised care being developed without the input of nurses, midwives and health visitors. Good practice in the areas of organisational change, innovation or work re-design always advocates where possible the involvement of staff affected by any changes in practice or ways of working. It is questionable whether research is required to establish that such well-recognised principles also apply in this instance.

The evidence as to whether standardised care in general improves patient outcomes or their experience of health care is equivocal. Although not a specific remit of this research, some reviews of evidence on the impact of standardised care on patients were analysed. The benefits of standardised care seem to be assumed, rather than proven. It is imperative to know whether using standardised care really does improve patient health outcomes, particularly given the costs and complexities of development and implementation highlighted by this research.

Research recommendations:

1. Commission research to investigate whether using standardised care does improve patient outcomes and patients experience of care.

2. Examine patient involvement in the development process, whether it is appropriate, feasible and adds value, and make recommendations for improving the patient voice in decision-making about standardised care.

3. Explore the patient perspective on standardised care as a communication tool and whether explaining that care is given in accordance with standards facilitates patient understanding, control and choice.

8.3.6 Clinical processes amendable to standardisation

Not all clinical tasks or situations are equally suited to standardisation and as our research shows, developing standardised care can be a costly and time consuming process. This means that careful consideration needs to be given to the clinical process/settings in which standardised care is deemed most appropriate. Our work, in line with other health care and wider organisational literature (e.g. Lawton & Parker, 1999; Perrow, 1967), indicates that routine, predictable and high risk situations and where there is a robust evidence, are more amendable to standardisation than situations characterised by complexity and uncertainty.

There is agreement amongst researchers that the best response to conditions of uncertainty and unpredictability is to design work so that employees are 'given the necessary skills, information and freedom to respond to unforeseen circumstances' (Cummings & Blumberg, 1987). Unpredictability requires that staff use their skills and knowledge to manage more complex demands. Not all forms of standardised care are appropriate in such situations; however, they can still be useful prompts in setting out macro processes and goals, rather than giving detailed instructions. Greater unpredictability requires that staff have the latitude to use knowledge and intuition to determine the most appropriate course of action.

This evidence, taken in conjunction with the likely costs and benefits of standardised care, suggest that policy makers, managers and practitioners should consider other quality improvement mechanisms, and not use standardised care as the default option.

Policy recommendation:

> The need to understand the conditions of uncertainty and unpredictability should be clearly articulated in guidance about standardisation, to enable informed decisions about when it is appropriate to initiate standardised care.

Practice recommendations:

1. There needs to be a thorough assessment of whether standardised care is appropriate based on local evidence about certainty and predictability.

2. The dimensions of risk, predictability and evidence should be taken into account when deciding to invest resources in standardised care.

3. Trusts, teams or wards need to be clear about whether the clinical process and setting are appropriate, and that the likely costs and resources needed to develop and implement standardised care are secured.

Research recommendations:

1. Compare the effectiveness of standardised care with other quality improvement tools.

2. Further research is needed to identify which forms of standardised care are desirable and attainable in different situations and specialities.

8.4 Challenges to standardised care in the future

This chapter concludes by considering the implications of two changes - in the shape and skills mix of the workforce and the demographics of the patient population - on the future of standardised care. These inter-related changes are likely to fit within the broader vision of a locally-led NHS proposed by Lord Darzi and impact upon 'what sort of organisation' the NHS will become over the next decade.

8.4.1 Changes in the workforce

The NHS Plan (2000) predicted that old demarcations would be shattered, that appropriately qualified nurse, midwives and health visitors would be empowered to take on new roles. This has happened, not just with new and expanded roles, but with an increasing skills mix in teams managed by these staff groups.

Further changes in the workforces are anticipated in Skills for Health (2008) which predicts a transformation in the workforce over the next ten years. The strategic intent is for a significant percentage of jobs in '*new roles*' at Band 4 level (assistant practitioner) in the NHS Agenda for Change pay system, with new divisions of labour to support service modernisation and a *'flattening of the current demand for qualified staff in 'traditional' professional roles.'*

An increase in the number of less qualified, skilled and knowledgeable health care staff has considerable implications for standardised care, as well as the future of the NHS, per se. Standardised care could underpin the next transformation, with less skilled staff performing predictable, routine, low risk tasks in accordance with explicit, transparent protocols that prescribe '*what should be done and when to refer on*' to more specialist or experienced staff. In this way, standardised care sets the parameters for their role and delegated decision making.

However, this raises the question as to whether such flattening of skills is appropriate. Care given by lower grade staff, with less clinical skill and expertise, and adhering to strictly implemented standardised care, has the hallmarks of 'bad rules' with the attendant risks of low job satisfaction and poor well-being for these staff.   The challenge for policy makers, managers, educators and practitioners is to achieve a balance between the degree of formalisation, patient safety and staff well-being.

8.4.2 Demographic changes

The second, inter-related challenge is the characteristics of the patient population. The age profile of the population is changing with consequent implications for health and social care. People are living longer with enduring, often complex conditions; and more high risk, vulnerable women are seeking maternity care (Blake, 2008); and the increasing proportion of older people are more likely to have complex health needs that are not amendable to standardisation and single problem guidelines (Boyd *et al* 2005). All these patients require care from experts, who are able to use their discretion and intuition to practice the art and science of nursing, midwifery or health visiting.

8.5 Summary

As with many policy initiatives, a balanced approached needs to be taken towards standardised care. This research has illustrated both the benefits of expanded roles, and the threat of control; the high cost of development and the importance of involvement for autonomy, for example.

The research has also shown just how significant standardised care seems to be for the majority of the NHS workforce, and by assumption, the NHS as whole. Standardised care is central to the working practices of nurses, midwives and health visitors, in different settings, across the range of specialities and activities. Providing care in accordance with formal, written documentation is part of the history and culture of these professions, and is also integral to current, evidence-based practice with research embedded within protocols, clinical guidelines and care pathways. Standardised care has also empowered nurses, midwives and health visitors to expand their roles and contribute to new services.

Standardised care is now so pervasive that it seems to have become a taken-for-granted way of working in health care. This is why it was, and continues to be, timely to examine the costs, benefits, challenges and impact of standardised care on staff and patients. This research has provided a starting point by quantifying for the first time the hidden cost of developing, implementing and monitoring standardised care; by exploring the facilitators and barriers to adoption and sustainability; and by identifying positive relationships between the properties of 'enabling rules' (i.e. involvement, transparency and flexibility) and autonomy, job satisfaction and well-being. Considering the prevalence of standardised care within one of the largest employers in the world, then it would seem to be crucial to optimise this way of working, so that standardised care is part of an enabling, learning organisation rather than a coercive bureaucracy. If organisations introduce standardised care inappropriately (e.g. in inappropriate settings, without enabling design characteristics, and/or without taking into account cultural and organisational change factors), then the initiative may well fail.

It is equally important to establish whether standardised care does improve patient experience and outcomes, as the current evidence is limited, with one Canadian study reporting that only 5% of guidelines had been evaluated to determine their impact on health outcomes (Graham, Beardall, Carter *et al* 2003).

Finally, standardised care raises some wide ranging and fundamental questions about the shape of the workforce, healthcare organisations and the NHS in the future.

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Appendix 1a: Method - Opinion leader interviews

During 2004-2005, semi-structured interviews were held with a purposive sample of 35 opinion leaders, able to offer practice, policy and academic perspectives on protocol-based care. The opinion leader interviews were conducted at the beginning of the research when protocol-based care - as the title and subject for the research - was used rather than standardised care.

The appendix contains a description of the recruitment procedures, the methods used to obtain and analyse the qualitative data, and the limitations of the opinion leader interviews. A full report of the opinion leader interviews is available from the authors.

1.1 Purpose of the opinion leader interviews

The purpose of the interviews was:

1. To gather and assess existing evidence on protocol-based care in nursing, midwifery and health visiting through a series of interviews with experts (identified in consultation with the expert panel) about the development and implementation of protocol-based care; and about the ways that nurses, midwives and health visitors contribute to protocol-based care.

2. To provide an overview of current thinking about the contribution and impact of protocol-based models of care.

3. To gather background information on other aspects such as measures of quality of care, unpublished research and professional activities relevant to study.

1.2 Characteristics of the opinion leaders

1.2.1 Defining, identifying and recruiting opinion leaders

The aim was to identify a range of opinion leaders able to offer policy, practice, patient or academic perspective on protocol-based care. Opinion leaders were defined in three main ways. These were by their:

1. Role in national government or professional organisations.

2. Track record of publications or presentations about protocol-based care.

3. Reputation, in that they were nominated by members of the expert panel.

A few people were targeted for their particular expertise, such as members of the legal profession. A total of 91 individuals or organisations were identified using a mixture of systematic and opportunistic strategies, including a search of the Internet and consulting members of the expert panel established for the study. Table 1.1 shows the strategies used to identify opinion leaders.

Table 1.1. Systematic and opportunistic strategies used to identify opinion leaders.

Strategies	Number identified
Search of the Internet using the Copernic Agent for authors and conference presenters	23
Linked to role within a specific policy making or influencing organisation	22
Nominated by, or were members of the expert panel	18
Knowledge of research team, including opportunistic meetings at ICP, SDO and midwifery conferences	17
Snowball – suggested by interviewees	11
Volunteers	2

Of the 61 opinion leaders approached to participate in a telephone or face-to-face interview, 15 declined. This was for number of reasons including lack of expertise, because protocol-based care was not a term or tool used in their setting or they were too busy to participate. One organisation representing patients was contacted, but they also declined saying that protocol-based care was a primarily a staff concern.

1.3 Data collection and analysis

1.3.1 Interview procedures and phases

The interviews were conducted using an interview guide (see annex 1) that was piloted with four informants and refined following feedback from the pilot and the expert panel. All the opinion leaders received a copy of the interview schedule in advance, with the participant information sheet which

outlined the whole project and the purpose of the interviews. Participants were guaranteed anonymity. Interviews were conducted in three phases:

1. Piloting of the interview schedule during autumn 2004.

2. Interviews with 22 opinion leaders offering a policy or academic perspective between January and August 2005.

3. Interviews with 9 NHS staff between June and November 2005.

Most of the interviews were conducted face-to-face and there were nine telephone interviews.

1.2.2 Background of the opinion leaders

The participants drew upon a wealth of experience working in health and social care in the United Kingdom. Most worked in the NHS but at least one had current experience in social care and the independent sector. Many drew upon twenty to thirty years of work experience in a variety of roles. The opinion leaders were categorised according to their current role as practitioners, policy makers or influencers, and as academics.

Table 1.2. Work settings – organisational contexts of the opinion leaders.

Work setting	Number of opinion leaders
NHS – Hospital	8
NHS – Primary Care	2
NHS – Strategic Health Authority	1
Higher Education Institution (HEI)	9
Government body	6
Professional association/body (PB)	3
Care home	1
Joint – NHS/HEI	3
Joint – HEI/NHS Primary Care	1
Joint – PB/NHS Primary Care	1

1.3.2 Coding the transcripts

The interviews were transcribed verbatim by a commercial company. The transcripts were checked against the audio recording to ensure accuracy of transcription. The 35 transcripts were then imported into QSR NVIVO

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(version 2), a software package, designed to facilitate storage, coding and retrieval of qualitative data.

The data was coded using a thematic framework. The coding framework was developed iteratively; using an inductive and deductive approach with categories derived from the interview guide and emerging themes. This gave 14 top level descriptive and conceptual categories.

The background or attributes of the opinion leaders were coded using demographic details, such as specialty, their current role and employment sector; and whether they had direct or indirect experience of protocol based care.

Transcript coding was completed by one person and consistency of interpretation was checked by using one or more independent coders.

Table 1.3. Current role and perspective on protocol-based care.

Current role	Number of opinion leaders
Practice:	
Practice development	6
Front line practitioner	3
Senior manager	2
Policy:	
Policy maker	6
Policy influencer	3
Academic:	
Researcher	6
Lecturer	3
Joint:	
Practitioner & researcher	3
Manager & practitioner	1
Policy influencer & practitioner	1
Researcher & lecturer	1

1.3.3 Analysing the qualitative data

The qualitative data was analysed using a framework approach recommended for policy initiatives (Ritchie & Spencer 1994). This provided a systematic way of illuminating the diverse views expressed by interviewees from practice, policy and academic perspectives. The framework approach comprises five stages. These are:

1. Familiarization – gained through listening and reading the transcripts.

2. Identifying a thematic framework – this was the process of agreeing and refining the coding framework described above.

3. Indexing - all the interview data was coded using NVivo.

4. Charting – this involves interrogating each coding category in the thematic framework. See annex 2 for an example of a chart.

5. Mapping and interpretation – which involves drawing the dataset back together as a whole to explore patterns and associations. The findings in the research report (Patterson *et al*, 2008) and the opinion leader interview report represent our interpretations of the breadth and depths of opinions expressed by the 35 opinion leaders.

Appendix 1b: Interview guide with probes

SDO Protocols: Opinion Leaders Discussion Guide

Introduction to project

Give a brief background to the project. Explain that the purpose of the meeting at this stage is to have an open conversation with opinion leaders about protocols and protocol-based care (PBC) in general, but with a particular interest in Nursing, Midwifery and Health Visiting.

Definition

1. **How would you define protocols?**

   (Other terms may be clinical or care protocols, management protocols, nursing based protocols, and evidence based protocols.)

2. **How would you define protocol based care?**

   (Some tensions highlighted in the definitions include: control v choice, standardisation v medicine as an art, directive v reflective practice.)

3. **How is PBC different (or not) from care pathways / integrated care pathways / clinical guidance?**

   (Probe for anything uniquely identifiable about PBC v other approaches, other approaches could include medical algorithms, triage, clinical pathways what was there before? How has PBC moved things on etc.)

4. **How has PBC come about? / where did the idea originate?**

   (Probe for original sources/evidence/research, original aims etc, any major developments or changes in thinking about PBC and why.)

5. **What is/are the stated aim(s) of protocol based care (as it is understood today)?**

   (Probe official line? Improved patient care? Improved job roles? Cost cutting?)

6. **To what extent is there a degree of consensus about PBC?**

   Probe e.g. PBC Policy/Strategy? [national, regional, local? By specialism? By profession?] PBC development? PBC implementation?)

7. **Ideally, how should a protocol be**

a. **developed,** *(Prompts include national v local based on expert systems (directive) v reflective practice; enable innovative practice v risk minimisations, knowledge capture.)*

b. **implemented,** *(Prompts might include how implementation should be managed, how they should go about gaining buy in from staff, how they should approach necessary training, how they should deal with problems*

during implementation.)

c.   **operated?** *(Prompts might include, how they should be portrayed i.e. mandatory v guidelines etc – interesting to explore views about nurses v doctors.)*

(probe for specific approaches, recognised good practice etc)

8.   **To what extend does that match what happens in practice?**

(Probe issues of legacy PBC approaches? Resistance? Clarity of evidence? Barriers to PBC development/implementation etc.)

9.   **(NB Not sure about something on 'variance of care' in here?)**

Use of PBC

10.   **In your opinion, how widespread is the use of PBC in the NHS?**

(Ask them to quote specialisms if possible.)

11.   **Is there variation in the extent to which PBC is used across medical specialisms?**

12.   **If so, what are they? Why do you think these differences exist?**

(Probe for: political, practical, professional, settings where protocols work particularly well, settings where they work less well, and if so, why then work well/less well in different specialisms? Probe for any reference to development and/or implementation of protocols in the examples given etc.)

13.   **To what extent do each of the three groups use protocols?**

14.   **Are there variations in the extent to which protocols are used between the three groups?**

15.   **If yes, what are the reasons for these differences?**

(Probe for: political, practical, professional, settings where protocols work particularly well, settings where they work less well, why they work well/less well in different professions/job roles? Probe for any reference to development and/or implementation of protocols in the examples given, etc, probe for levels of involvement in process)

16.   **Has there been evidence of tensions between providing standardised PBC versus opportunity for reflective practice and locally developed need?**

(Probe for: use of embedded research model (i.e. expertise and evidence embedded in the design which can result in more directive practice in delivery) v design which allows for more of an opportunity for reflective practice in delivery)

17.   **If yes, what has been the impact?**

(Probe for: How have the tensions been resolved? If so, how?)

18. **Has there been evidence of tensions between the need to be innovative versus the need to minimise risk?**

    (Probe for: the tensions between individual freedoms vs. the need to minimise risk when new people join the team; the 'need' for a safety mechanism for the changing clinical role for nurses)

19. **If yes, what has been the impact?**

    (Probe for: How have the tensions been resolved? If so, how?)

20. **To what extent has technology played a part in the introduction of PBC?**

    (Probe for: Is it more effective at supporting one model of PBC over another? Is it used for both reflective and directive practice?)

Benefits and Barriers

21. **What do you see as the main benefits of PBC approaches?**

    (Probe for: Differences across medical specialisms, professions, job roles, quality of care, patient experience, methods of PBC development, methods of PBC implementation)

22. **What are the main drawbacks of PBC approaches?**

    (Probe for: Differences across medical specialisms, professions, job roles, and quality of care, patient experience, methods of PBC development, methods of PBC implementation)

23. **What are the main drivers for the implementation of PBC?**

    (Probe for: Differences across medical specialisms, professions, job roles, quality of care, patient experience, methods of PBC development, methods of PBC implementation? Role play by the NSF; other agendas [National? Regional? Local? Professional? etc] other (HRM) changes [e.g. ways of working, retention, flexibility etc])

    (NB we might want more in here from the Occ Psych perspective and other org initiatives?)

24. **What are the main barriers to the implementation of PBC?**

    (Probe for: differences across medical specialisms, professions, job roles, quality of care, patient experience, methods of PBC development, methods of PBC implementation? Other agendas [National? Regional? Local? Professional? etc] other (HRM) changes [e.g. ways of working, retention, flexibility etc]).

    (NB we might want more in here from the Occ Psych perspective and other org initiatives??)

	Evidence and prospects
25.	**In your view, what is the state of the evidence base for PBC at a general level?** *(Probe any issues raised about national agendas, patient care, professional development, cost cutting etc)*
26.	**Are there particular areas where the evidence base is recognised as (or believed to be) stronger/very strong?** *(Probe for which areas and why? Or general view for lack of variation in evidence? Or evidence base patchy/not really known? Or evidence base too protocol specific to tell?)*
27.	**What are the prospects for PBC approaches over the next five years? / Next 20 years?**
28.	**Why do you say that?**
	Anything Else?
29.	**Check for details of other opinion leaders we should talk to/reference etc.**
30.	**Check for anything not covered.**

Appendix 2a: Method - systematic literature review, development and implementation

One of the objectives of the research was to undertake a critical review of the literature to examine existing evidence on protocol-based care development and implementation with specific reference to the roles of nurses, midwives and health visitors. This annex specifies the methodology which drew upon systematic literature review and qualitative heritages. There were three elements to the review, each of which followed the standard systematic review method. The elements were:

1. Developing search strategies for protocol-based care

2. Targeting the search on relevant databases and expanding the search to include the variants of protocol-based care.

3. Appraising papers about development/implementation and impact – separately and differently.

2.1 Applying systematic review methodology to protocol-based care

Systematic literature reviews aim to provide an objective, comprehensive summary of what is known about a specific topic using an explicit, replicable method. This involves constructing a clearly-defined research question with inclusion and exclusion criteria, comprehensive searching to identify all relevant literature, quality assessment of selected studies, extraction of relevant data from these studies, and synthesis of the data to make explicit the existing knowledge/research base.

A standard systematic review model was used which comprised five stages. These were:

1. Definition of the research question

2. Identification of potentially relevant literature (literature search)

3. Study selection and quality assessment

4. Data extraction

5. Data synthesis

2.1.1 Defining the research questions

Getting the question right is 'the most important step in doing a review . . . [because] poorly focused questions lead to unclear decisions about what research to include and how to summarise it' (Higgins & Green, 2005: 59).

The questions for this research were derived from the research objectives. They were to:

1. examine the ways that nurses, midwives and health visitors *contribute* to the development, implementation and audit of protocol-based care

2. explore the *impact* that contributing to protocol-based care has upon nurses, midwives and health visitors.

2.2 Identifying relevant studies

In March 2005, 20 databases were searched using 'protocol-based care' as the search term. The aim of the first literature search was:

a) to map the body of knowledge,

b) to identify terminology in readiness to expand the search terms for later searches, and

c) identify journals for hand searching.

Searches using the term 'Protocol based care' produced a particularly poor yield, with only 75 references identified across 20 electronic databases. On further examination, the vast majority of these references were not relevant to the present study.

The first searches confirmed that Protocol-based care was a rarely used term in the literature. In order to identify relevant studies the review team had to adopt a flexible, exploratory and reflective approach. The iterative process of identifying relevant literature and selecting studies is reported in chronological order. This is to show the reflective approach to the search results, with the paucity of literature about protocol-based care requiring a different strategy that involved identifying the variants of protocol-based care and then targeting the next literature search on protocols, pathways, guidelines and integrated care pathways in nursing, midwifery and health visiting.

2.2.1 Targeted search: nursing sources and 'variants' of protocol based care

The second phase of searching consisted of purposive searches to find relevant literature. Eight 'nursing related' databases and the search engine Google, were searched in May 2005 using combinations of the variants of protocol-based care, namely protocols, guidelines and care pathways. Table 2.2 contains the hit statistics for this exploratory search. It shows that many more references were identified using variants of protocol-based care as the search terms. The relevance of these studies was highly variable, with large numbers unrelated to the research question.

Table 2.1. Hit statistics from search for variants conducted in May 2005

Database	Protocol Based Care	Care Pathway*	Protocol*	Guideline*
	No. of hits			
British Nursing Index/RCN	6	103	582	2,701
CINAHL	6	292	11,416	20,983
Cochrane	0	10	3,852	1,231
EMBASE	14	143	106,369	87,668
HMIC	3	234	425	2,520
MEDLINE	16	307	166,970	100,089
SCI & SSCI	12	134	102,899	76,071
Google	1580	46,300	69,300,000	9,320,000

A final search was conducted on five databases which targeted the most relevant journals for nursing and midwifery (British Nursing Index (UK), CINAHL, EMBASE, Medline and Web of Science). Three search terms were used to target relevant meanings and allow for terminology being used interchangeably. The search terms were i) protocol only, ii) protocol and guideline and ii) protocol and pathway. The results of this search are shown in table 2.3.

This supplementary, targeted search produced 8,139 titles and abstracts that were imported into Reference Manager Professional Edition Version 11, a reference database for storing, managing and searching bibliographic references. Due to problems with the OVID import filter for CINAHL, a manual search was conducted which resulted in the removal of 1,491 duplicate references, giving a total of 6,648 titles and abstracts.

2.2.2 Study selection – first sift for the targeted search

A first sift of titles and abstracts was performed using the search facility on Reference Manager to identify studies most likely to answer the research questions. The search terms were agreed by three reviewers and identified titles and abstracts that:

1) referred to the development and use of protocols, pathways and guidelines and

2) included reference to at least one of a range of qualitative and quantitative research designs.

These were identified using MESH terms, plus audit and evaluation to reduce the likelihood of descriptive studies. The agreed terms were used by two reviewers who   independently searched the 'all non-indexed fields' on Reference Manager to confirm the number of papers in each category.

Table 2.2. Results of the targeted search of five 'nursing' databases using expanded search terms that covered the variants of protocol-based care.

DATABASE NAME AND DATE COVERAGE	REFERENCES	DUPLICATES DELETED when imported	NOTES
1. BRITISH NURSING INDEX 1985-MARCH 2005			
▪ Protocol only	582	-	
▪ Protocol and guideline	128	-	
▪ Protocol and pathway	10	-	
2. CINAHL 1982-MARCH 2005			Nursing journal subset only POOR QUALITY LOAD:
▪ Protocol only	2,956	501	ALL PUBLICATION DATES
▪ Protocol and guideline	444	90	HAD TO BE RE-DONE
▪ Protocol and pathway	67	5	
3. EMBASE			Nurse/nurses/ nursing subset
▪ Protocol only	1,313	40	
▪ Protocol and guideline	315	27	
▪ Protocol and pathway	37	1	
4. MEDLINE 1966-MARCH 2005			OVID Medline Nursing journal subset only
▪ Protocol only	1,996	2	
▪ Protocol and guideline	597	24	
▪ Protocol and pathway	86	90	
5. WEB OF SCIENCE			
▪ Protocol only	500	202	
▪ Protocol and guideline	185	107	
▪ Protocol and pathway	25	13	
TOTALS	**9,241**	**1,102**	

2.2.3 Additional searches for integrated care pathways

Two additional searches for integrated care pathways were conducted in 2006. Integrated care pathway is a specialist term and variant of protocol-based care which has a dedicated journal, the Journal of Integrated Care Pathways.

In February 2006, five databases (British Nursing Index (UK), CINAHL, EMBASE, Medline and Web of Science) were searched using the term integrated care pathway. This search produced 379 titles and abstracts, of which 138 were duplicates of the existing data. The remaining 241 references were subject to the same first study selection process, using the search facility on Reference Manager, to identify relevant and methodologically rigorous papers.

Twenty-six issues of the Journal of Integrated Care Pathways were hand searched in June 2006. This journal started in 1997 as the Journal of Managed Care, becoming the Journal of Integrated Care in 1998 and the Journal of Integrated Care Pathways in 2000. Three issues are published each year. A total of 11 papers were identified as containing data likely to answer the research questions. These references were added to the dataset on Reference Manager.

2.3 Study selection: sifting titles and abstracts

The electronic literature searches, the Reference Manager sift, the hand search of the Journal of Integrated Care Pathways, plus one paper found serendipitously, produced a total of 3,872 titles and abstracts.

Conventional systematic review methods advocate the application of a Study selection aims to be systematic, replicable and free from bias. A proforma containing inclusion and exclusion criteria derived from the research questions, was piloted, discussed and revised by the review team. The reasons for including or excluding papers were explicit to ensure consistent interpretation. For example, the questions asked:
- Does the paper specify the involvement of nurses, midwives in the development or implementation of some form of protocol-based care?

- Does the paper contain data on outcomes and if so, are they staff, patient, organisational, cost, safety or other outcomes?

- Is the paper evaluative (research or audit) and not just descriptive?

Four members of the review team sifted the 3,872 titles and abstracts using the bespoke proforma. Each abstract was reviewed by one reviewer and a 10% sample were screened by a second reviewer as recommended by Petticrew & Roberts (2006: 120). This showed an average 89%

agreement between reviewers which was considered an acceptable level of inter-rater reliability.

Not all the selected papers could be, or were obtained. A total of 262 papers published between 1976-1989, were excluded because they were published in a very different policy era and they also pre-dated electronic publishing and were difficult to obtain. Forty-one non-English papers were excluded to avoid translation costs and the British Library were unable to supply 19 papers.

This meant that 859 papers were included which either specified the involvement of nurses, midwives or health visitors in development or implementation of a variant of protocol-based care or contained data about the impact of variants of protocol based care on staff. Table 2.4 summarises the type of outcome data identified.

Figure 2.1. QUORUM flowchart for the review

	Total citations from electronic database searches (n=6,648)
Hand search of Journal of Integrated Care Pathways (N=11)	
Citations from additional database search for integrated care pathways (n=241)	
Serendipity (n=1)	
	Total potentially relevant studies (n=6,901)
	First sift using inclusion criteria with Reference Manager
	Total studies after first sift (n= 3,872)
	Application of inclusion criteria to titles and abstracts (n= 3,872)
	Studies excluded if published before 1990 (n=262), not published in English (n=41) and unobtainable from British Library (n=19)
	Total studies after second sift (n=859)
	Studies excluded not published in English (n=3)
	Application of inclusion criteria to full papers (n=856)
	Total studies containing data about development and implementation (n=293)
	Source of included papers: USA (n=136), UK (n=117) Canada (n=11), Others (n=12) European (n=8), Australia (n=9)
	Final total of UK studies appraised (n=33)
	Final total of studies with useable data about impact (n=64)

2.4 Data extraction

The data extraction stage involves collecting the most important data from the 859 included studies to answer the research questions. A bespoke data extraction form was pilot tested with ten papers, discussed, shortened from eight to two pages and then tested again with ten different papers.

Table 2.3. Categorisation and distribution of outcomes reported for protocol-based care in the 859 included papers.

Type of outcomes:	Number of papers
Staff/team/profession impact	293
Organizational impact	90
Costs	71
Safety	118
Patient outcomes	465
Other	45

Following the pilots, it was agreed to categorise the papers into two sets:

1. those containing usable data about the development and implementation of protocol-based care

2. those containing usable data about the impact of using protocol-based care on nurses, midwives and health visitors.

The data extraction form instructions emphasised the importance of real, usable data, rather than just passing mention or proxy observations. Data extraction was completed by one reviewer and a 10% sample was checked by a second reviewer to ensure consistency of interpretation.

A total of 319 papers were assessed as meeting the inclusion criteria for development and implementation of variants of protocol based care or the impact on staff.

2.5 Data synthesis

The final stage of the systematic literature review process involved drawing together, contextualising and interpreting the findings from the separate studies (Greenhalgh, Robert, Bate, Kyriakidou, Macfarlane & Peacock, 2004). At this stage, the papers about development - implementation and impact were reviewed separately and in different ways. This was to capture

the practitioner knowledge in the development/implementation papers and the research about impact on staff outcomes.

2.6 Development and implementation

There was usable data about development and implementation in 293 papers. A representative sample (33/117) of the UK papers were analysed in detail using a dual approach. Two reviewers, using an inductive or deductive approach analysed 33 papers. The inductive analysis was undertaken using the Qualitative Assessment and Review Instrument (QARI) software designed for synthesis of qualitative research but used in this case to synthesise narrative data. The deductive approach compared the 12-step framework produced by the Modernisation Agency and the National Institute for Clinical Excellence (MA/NICE 2002) with the experiences described in the papers.

The process was stopped when data saturation was reached, with no new themes emerging from the papers. The themes were scrutinised and verified by a third, independent reviewer who audited the review of qualitative, narrative data.

2.7 Impact

The 64 included research papers about impact were appraised in a conventional way, with the findings reported in tables in appendices 2f and 2g.

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Appendix 2b: Table of findings: Development

Table 2.4. Development: details of 33 UK included papers using the 12-steps and additional ones derived from data (a)

Table 2.4	Ref ID	Authors Publication Year	a) Protocol aim b) Terms used c) Protocol users	a) Study design b) Study duration c) Study setting d) Population e) Primary focus on staff	1) Select and prioritise topic 1a) Secondary purpose 2) Set up a team 2a) Meetings 3) Involve patients and users	4) Agree objective 5) Build awareness and commitment 5a) Trust approval 6) Gather information 6a) Literature review	7) Baseline assessment 8) Produce the protocol-based care 8a) Documentation
	1	W.W. Ayris (2002)	a) Permit the verification of expected, out-of-hours death at home by district nurses b) Procedures, protocol c) Registered nurses on the out-of-hours district nursing team	a) Descriptive case study b) Not stated c) Primary care d) Not stated e) No – development process	1) Delays in formal verification of death by medical providers when occurs out-of-hours which increases stress for newly bereaved, call handling staff and district nursing service. Arose from a difficult situation - an 8 hour delay. 1a) Allow removal of parenteral medication and also to provide a more supportive service to carers. Expansion of nursing role. 2) No, author used protocol developed in local community hospital and consulted GP about physiological signs of death. 3) Not stated.	4) Not stated 5) Discussed problem with a local GP and manager of local deputising service, held meeting with local funeral directors: agreed verification by nurses was feasible and desirable. 5a) Final version of protocol sent to Trust management and checked by legal team. Also distributed to staff at senior and 'grass roots' level for comment, local GPs, deputising service and management of main funeral directors and local branch of Funeral Directors Association. Received positive feedback from local medical committee. 6) Used protocol devised in local community hospital about nurse verification of death. Investigated legal position and guidance produced by professional bodies. 6a) Literature search – nothing relevant found.	7) Not stated 8) Procedures for verifying and not verifying death included in the article. 8a) Form devised to notify primary healthcare team of the death.

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	2	D.R. Baird, M. Henry, K.G. Liddell, C.M. Mitchell & J.G. Sneddon (2001)	a) To overcome an infection control problem b) Protocols, policies, procedures, integrated care pathway, care pathway protocols, checklist c) Multi disciplinary team	a) Descriptive case study b) Not stated c) Ophthalmology Unit d) Not stated e) No, description of application of hazard analysis critical control points (HACCP).	1) Problem – 4 cases of early infective endophthalmistis following cataract surgery over a 5 month period. Recurrence with 4 more cases in next 8 months after implemented changes recommended by infection control. 2) Infection control team formed to review and document process of patient journey. Project team, split into 3 working groups comprising nursing, medical ophthalmology staff and members of infection control. Each group meet formally on average twice weekly. 3) Not stated. Patient information leaflets revised.	4) Yes, to examine current practice, assess against guidance, and draft a protocol using an agreed template. 5) Discussed issues with relevant professionals. *'It was recognised that staff felt threatened by such a close examination of their work activities, and therefore reassurance and explanation given throughout'* (p18). 6) Reviewed current literature and consulted widely with colleagues in other units using a telephone survey and with local expert opinion.	7) Investigation by infection control team found polices and operative procedure between surgeons were not standardised. 8) Development of care pathway protocols (CPPs) fundamental to HACCP approach. Total of 29 protocols developed over a 2 month period. Example in the article.
	3	L. Bell, Solieri, A. West, K. Burgess & T, Dowdeswell (1997)	a) Standardise nursing care throughout hospital of patients with fractured neck of femur. b) Nursing protocol, clinical care protocol	a) Case study with pre and post design b) Two years c) Hospital d) Fractured neck of femur (N=700) e) Yes – outlined process and benefits for nurses	1) Medical audit showed that 48% fractured neck of femur patients were not receiving care from specialist nurses. 1a) Systematisation of patient care, to prevent replication of key aspects of care and reduce complication rates. 2) Multidisciplinary working group comprising nurses, surgeons, anaesthetists, radiologists,	4) Yes, to allocate responsibility for specific aspects of care to particular nursing groups and improve patient outcomes. 5) Audit Dept assisted with data collection and analysis. 6) Review of all current activities using the blue printing model to track care	7) Exploratory clinical audit using 80 decision making points. Historical review of 1-year sample of patient notes. 8) Clinical protocols devised to rectify deficiencies in care identified at

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			c) Nurses		occupational therapists, physiotherapists and service managers. Also specialist nursing groups working in A&E Dept, Orthopaedics Dept and Dept of Medicine for the Elderly. 3) Not stated	and 80 decision making points.	decision points. 8a) Protocols amalgamated and put into a proforma that went from A&E to discharge and was included in the medical notes.
	4	L. Birchall, L. Street & H. Clift (2002)	a) Develop a Trust wide approach to use of Topical Negative Pressure (TNP) for wound healing b) Protocol, procedure c) Nurses	a) Descriptive case study b) 11 months c) Two hospitals d) Not stated e) No – developing a Trust wide policy	1) To provide Trust wide approach. 1a) To meet increased demands for clinical support from the professional development sister who instigated use of TNP on Burns and Plastic Surgery Unit. 2) Yes, working party comprising professional development sister, Trust tissue viability nurse, tissue viability clinical nurse specialist and practice development nurse. 3) Not stated	4) Yes, action plan and project timescale agreed 5) Yes, Initial draft protocol circulated to key stakeholders. 5a) Yes, protocol subjected to Trust's verification system and approved by Chief Nurse. 6) Not stated	7) Not stated 8) Not stated
	5	J. Bowman (2000)	a) Expanding role and introducing nurse prescribing b) Treatment protocols, protocol nurse prescribing c) Dermatology nursing team	a) Descriptive case study b) Not stated c) Nurse-led and administered day care dermatology unit with consultant supervision d) Not stated e) No – development of unit and nurse	1) Increasing incidence of skin disease and providing service in a large rural catchment area. 1a) Closure of dermatology ward; increased referrals and spare capacity in the day care unit. Giving dermatology nurses more autonomy. 2) Implied from report of developing a formulary of drugs for nurse prescribing	4) Not stated 5) Not stated 5a) Permission to use formulary obtained from Trust's drugs and therapeutics committee. 6) Described hypothetical, 9 month trial conducted in 1994 about nurse prescribing in the Trust which compared nurse and	7) Not stated 8) Yes, protocol for each group of medicines 8a) Protocol specifies conditions, clarified responsibilities and offers guidance on

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				prescribing	which involved consultant staff and pharmacist. 3) Not stated	SHO with consultant (as control) treatment choices for 48 patients with eczema or psoriasis.	patient documentation and instructions for nursing/medial review.
6		A. Bruton & K. McPherson (2004)	a) To improve weaning of ventilated patients b) Protocols, structured protocol-driven approach, flow chart. c) All staff on ICU	a) Descriptive case study with some pre and post protocol data about staff perceptions b) Not stated – year before protocol embedded in practice c) General Intensive Care Unit in a Regional General Hospital d) Not stated e) Yes – part of setting up a multi disciplinary weaning team	1) To enable successful weaning from mechanical ventilation. 1a) Inconsistent approach due to consultant bias and dissatisfaction amongst nursing and therapy staff about lack of a weaning strategy. 2) Multi disciplinary weaning team, led by a research physiotherapist, established by consultant body. Team included 2 clinical nurses and 1 nurse educationalist. 2a) Meet regularly to review progress. 3) Not stated	4) Agreed at first team meeting. 5) Yes, consultation via staff questionnaire about weaning process. 6) Yes, published guidelines. 6a) Critical review of the literature found that protocol-directed weaning generally accepted as beneficial to patients but no consensus on the optimal protocol.	7) Collected data over 6 months about specific patient outcomes. 8) Yes, screening criteria produced for use daily as part of routine care. 8a) Criteria simplified and brightly coloured stickers used as visual cues
7		S.M. Carr, M. Lhussier & J. Wilcockson (2005)	a) Study comparing two approaches to service / practice development : introducing the Liverpool end of life	a) Comparative case study with interviews (N=32) b) 18 month implementation period c) 2 Primary Care Trusts d) Not stated e) Yes, transfer of	1) Service development – introducing the end of life care pathway. 1a) Comparing two implementation models: buying in expert time from specialist palliative care teams and buying out generalist time from the primary health care teams. 2) Not stated	4) Not stated 5) Not stated 6) Not stated	7) Both PCTs started with a similar baseline of specialist palliative care teams with clinical nurse specialists linked to specific general practices

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			care pathway b) Integrated care pathway c) Community nursing staff and general practitioners	knowledge from specialists to generalists	3) Not stated		focusing on ownership, change and sustainability. Site with 'buy in' of expert time – baseline audit of practice as recommended by LCP 8) Not stated 8a) Site buying out generalist time – modified LCP documentation.
	8	M. Christensen (2002)	a) Enable nursing staff to facilitate nurse-led chest drain removal independently of medical staff input b) Working standard, algorithmic model c) Suitably qualified 'E' and 'F' grade nursing staff ie completed the Entonox study day	a) Case study with a pilot b) Not stated c) Cardiac high dependency unit d) Uncomplicated 'fast track' elective cardiac surgery patients. e) England f) No – process of development g) None cited	1) Review of literature - empirical and anecdotal evidence about pain and discomfort with a chest drain *in situ.* 1a) Delays about removal when decision made by cardiac surgical team. Support within unit for nurses to make decision about chest drain removal. 2) Three-member steering group formed. 2a) Formalised meetings began after survey and literature review. Agenda: framework for the working standard, nurse eligibility criteria, patient inclusion/exclusion criteria and benefits 3) Not stated	4) Aim and 4 key objectives developed 5) Needed to gain support of four consultant cardiac surgeons. Detailed proposal to surgeons and algorithm for nursing staff. 5a) Approval by senior nurse 6) Telephone survey of 10 cardiothoracic ICUs with medical decision making in 8/10 units 6a) Yes, CINHAL & Medline 1984-1999 produced little evidence about nurse-led chest drain removal	7) Not stated 8) First draft with cardiovascular parameters prescribed by medical staff. 8a) Algorithm as a simple and easy-to-follow format, as a user-friendly tool.

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			and been assessed as competent				
	9	J. Clark, J. Day, E. Howe, P. Williams & A. Biley (1995)	a) Improve the immunisation uptake rate b) Protocol c) Health visitors	a) Descriptive case study b) Protocol developed over 12 months c) Health Visitor Development Unit in a Fund holding GP Practice d) Practice population e) No – part of project to improve immunisation	1) Increase the immunisation rate from 72%. 1a) Opportunity for health visitors to become involved in overall aims of the practice, to reach children in most need and contribute their knowledge of health needs of the local community. 2) Not stated 3) Not stated	2) Not stated 3) Negotiations with relevant stakeholders to meet policy and contractual obligations. 5a) Modifications to Health Authority policy about health visitor immunisations. 6a) Yes - review of the literature	4) Not stated 5) Not stated
	10	L. Davies (1996)	a) Improve the assessment and treatment of chronic leg ulcers b) Protocol, standard management protocol, guidelines c) Community nurses	a) Descriptive case study and audit b) Not stated c) Primary Care d) Patients with leg ulcers e) No – development and audit	1) Improve quality of care 1a) Reduce costs of assessment and treatment of chronic leg ulcers and also to free nurses' time for other tasks. Improve working relationships through sharing a common purpose ie regular audits. 2) Medical and Nursing Forum attended by hospital and community staff identified need for a multi-disciplinary audit. Working group of 2GPs, 3 District Nurses and Senior Nurse from the hospital, was established and an audit designed with assistance of the audit department. (3) No, but the protocol guidelines recommended that patients	4) Yes - determine prevalence of leg ulcers in community, assess introduction of a management protocol on nursing time and patient morbidity. 5) Consulted local consultant dermatologist. 5a) Protocol approved by local medical ethics committee. 6) Not stated	7) Assessing all patients over the first three month period. All patients then reassessed by a nurse and doctor and management decided. 8) Not stated

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					were involved in decisions about management and trained in all preventative and supportive measures		
	11	A.J.M. Davis, D. Bowman & H.A. Shepherd (2004)	a) Facilitate a fast track protocol-directed nurse-led iron deficiency anaemia (IDA) clinic b) Protocol, clerking sheet c) Nurse specialist (N=1)	a) Case study evaluation b) 15 months c) Outpatient clinic d) First 100 patients referred to clinic e) No – patient outcomes	1) To establish an open access clinic to primary care physicians so as to meet waiting times target. 2) Not stated 3) Not stated	4) Not stated 5) Inferred from establishment of the IDA clinic 6) Not stated	7) Analysis of historical data showed average 11 week waiting time from referral to diagnosis. 8) Yes, included in article.
	12	W. Dibb, J. Fawcett & R. Whall (1999)	a) Nurse-led pre operative optimisation to improve patient outcomes. b) Standardised protocol, flow diagram, guidelines c) Senior nurses: 5 years ICU experience, research	a) Descriptive case study b) Intensive Care Unit and High Dependency Unit c) District General Hospital d) High risk of peri-operative complications following major abdominal elective surgery e) No, development of protocol used in	1) Protocol developed for a randomised control trial (RCT). 1a) Intensive Care environment ideally suited to use protocols, nurses greater autonomy in decision making and opportunity to expand their roles. Financial reasons for nurses rather than doctors to carry out pre-optimisation. 2) Protocol devised and agreed by research team which consisted of 2 ICU consultants and four senior nurses. 3) Not stated	4) Not stated 5) Not stated 6) Not stated	7) Not stated 8) Yes, f low diagram included in the article.

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			qualification and ICU course	an RCT			
	13	A. Forbes, J. Berry, A. While, G. Hitman, A. Sinclair (2004)	a) Explore feasibility of district nurse led annual diabetes review b) Protocol, guidelines, treatment pathway c) District Nurses (DN) (N=4)	a) Pilot study with pre/post design with patient questionnaire, DN interviews and time log b) 6 months c) GP practices d) 12 frail older people with type 2 diabetes e) No – impact on patients and cost	1) Explore potential of district nursing led intervention – domiciliary annual diabetes review - for older people who are housebound or in residential care. 1a) Contextualise assessment to circumstances of each patient. 1) Not stated 3) Not stated	4) Yes, about impact of intervention on patient outcomes and feasibility within district nurse role. 5) GPs aligned to district nursing teams agreed to instigate treatment suggested by assessment. 6) Protocol developed from existing guidelines and research evidence.	7) Yes, baseline date collected before and during the initial assessment (N=12) and at 6 months follow-up (N=5). 8) Not stated
	14	K. Haw & N. Kitching (2000)	a) Structure care for patients with healed venous leg ulcers. b) Care protocol, protocol for patient-led care. c) District nurses	a) Descriptive case study with pre/post audit b) Not stated c) Not stated d) District nursing team e) No, description of development process	1) To formalise prevention and aftercare of patients with venous leg ulcers. 1a) To improve patient compliance and motivation. 2) Not stated 3) Indirectly, stated questioned patients about information received about prevention. Also formalised plans of care for individual goal setting.	4) Aim of protocol stated as providing patient-centred information and appliance of compression hosiery. 5) Not stated 6) Inferred, stated that research suggests that patient require knowledge for compliance.	7) Yes, annual caseload audit showed 51% recurrence rate of 2 or more episodes of ulceration. 8) Yes, stated devised protocol.
	15	A. Jeffery (2005)	a) To standardise practice in screening patients with Barrett's	a) Descriptive case study and pre audit b) Not stated c) Nurse-led clinic in an endoscopy unit d) Not stated	1) Risk of developing adenocarcinoma of the oesophagus. 1a) Results from audit which showed differences in practice and increasing number of	4) Not stated, reported that draft protocol was devised after the audit. 5) Yes, reported discussions with all consultants within the department and	7) Audit data from 155 patients in 2003. 8) Protocol in the article.

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			oesophagus b) Protocol, local guidelines c) Nurse endoscopist practitioner (N=1)	e) No, development of the protocol	patients with implications for resources to re-scope on an annual basis. Lack of consensus in unit about interval for surveillance gastroscopy. 2) Not stated 3) Not stated	agreement with the final copy which was distributed to all endoscopists. 6) Yes, from audit (see 7) and comment about similar surveillance rates in other endoscopy units.	
	16	Z.K. Johnson, P.G. Griffiths & M.K. Birch (2003)	a) Nurse prescription of topical glaucoma medication b) Protocol, flow pathway, written protocol c) Experienced E & F grade ophthalmic staff nurses (N=3)	a) Case study and audit b) 12 months c) Nurse-led glaucoma triage assessment clinic d) All patients referred with suspected glaucoma, except those with difficult diagnosis. e) No – new service and patient outcomes	1) To investigate possibility of nurses commencing treatment of patients with high pressure glaucoma on first visit. 1a) To assess accuracy of nurses' diagnosis. 2) Not stated, protocol for prescriptions agreed between medical and nursing staff. 3) Not stated	4) Yes, to validate protocol for nurse prescribing for newly diagnosed patients. 5) Not stated 6) Not stated	7) Not stated 8) Yes, flow pathway included in article. 8a) Proforma for nursing assessment produced.
	17	C. Johnston (2006)	a) To set a multi-disciplinary, explicit standard and record of care b) Integrated care pathway (ICP), local guidelines c) Multi-	a) Descriptive case study with audit and observation of nurses hand-over at 6 shift changes on the stroke unit b) Not stated c) Stroke rehabilitation unit and acute medical wards d) Stroke patients	1) Improve documentation of the integrated care pathway for stroke care in readiness for use on acute wards as well as the stroke rehabilitation unit. 2) Separate working groups for the various clinical themes within the ICP. ICP facilitator appointed to oversee introduction to acute medical wards. 3) Not stated	4) Not stated 5) Not stated 6) Not stated	7) Not stated 8a) ICP documentation formed entire medical and nursing record. Concerns about errors and inadequacies in nursing information: insufficient,

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			disciplinary team	e) Yes – adequacy of, and use of ICP documentation			mechanically copied and information wrongly documented.
	18	K. Kilburn (2002)	a) Develop nurse practitioner role to carry out procedure - flexible cystoscopy- beyond scope of practice b) Protocol c) Urology nurse practitioner and doctors	a) Descriptive case study b) Not stated c) Day case unit in a Hospital d) Not stated e) No – development of nurse-led service	1) Increasing incidence of bladder cancer with longer waiting times for urgent and non-urgent diagnostic cystoscopy. 1a) Trust supported development of nurse practitioner role. 2) No, stated that the consultant and nurse practitioner designed a protocol for carrying out the procedure. 3)No	4) Not stated 5) Not stated 6) Based on consensus of local opinion as no national guidelines available. 6a) Yes, searched Medline, UKCC, DH and NHSE databases 1995-2002; one relevant document about training for the procedure.	7) Not stated 8) Inferred from audit one year after introduction of service
	19	J. Kinley & S. Brennan (2004)	a) Encourage a consistent approach to oral care in one palliative care unit. b) Protocol, standard, protocol of care c) Palliative care nurses	a) Case study with a survey of knowledge and practice and retrospective audit b) Not stated c) 12 bed, in patient palliative care unit d) Not stated e) No – development process and audit	1) Mouth care underappreciated aspect of care and amendable to standardisation and audit. 1a) Initiated following dissertation work on oral care protocols by 1 of the authors. 2) No, the standard was written by the authors. 3) No. Information leaflets for patients, in the form of a bookmark, were created.	4) Yes, to implement best practice and educate providers to give consistent care. 5a) Standard approved by the audit department. 6) Questionnaire sent to all medical and nursing staff, including unqualified nurses about their practice, knowledge and documentation about mouth care. Results showed not uniform	7) Review of 50 patient notes as a baseline documentation with only 40% (n=20) containing any information about oral care. 8) Recommendations and source included in the article.

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						approach.	8a) Documentation – an oral assessment tool, an oral care plan and a protocol of care development with suggestions for management on the reverse - developed to support implementation.
	20	S. Laver, S. Preston, D. Turner, C. McKinstry & A. Padkin (2004)	a) Prescriptive intravenous insulin infusion protocol to control blood glucose b) Protocol, Bath Insulin Protocol c) Intensive care nurses	a) Descriptive case study with pre and post audit b) 6 months c) Intensive Care Unit in a District General Hospital d) Medical and surgical intensive and high dependency patients e) No – impact on patient outcomes	1) To reduce mortality among critically ill patients. 1a) To alleviate need for clinical judgement and the inherent errors in decision making. 2) Not stated 3) Not stated	4) Not stated 5) All medical and nursing staff encouraged to provide written and verbal feedback during the development stage. 6) Not stated	7) Not stated 8) Inferred from description of audit during development phase. 8a) Protocol and guidance notes modified in response to feedback at development phase.
	21	C. Macduff, B. West, S. Lawton, A. Leslie & M. Ironside (2001)	a) Facilitated development of nurse-led treatment for minor injuries b) Protocol, assessment	a) Case study and baseline audit b) Not stated c) Casualty Units in 9 Community hospitals d) Not stated	1) Development of new nurse-led treatments for minor injuries based on assessment/ treatment protocols. 1a) Provide sound basis for consistent care while acknowledging professional	4) Stated that through discussion, the MD working group targeted and then drafted protocols for 47 minor injury types suitable for nurse-led treatment. 5) Short term, project	7) Not stated 8) Example given in paper. 8a) Each protocol was developed as an A4 paper sized flow chart

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			and treatment protocols, flow chart, algorithm c) Senior casualty nurses and GPs	e) No – description of development and audit	judgement. 2) Multi disciplinary (MD) working party formed to develop the protocols. Membership then reduced to senior nurses from each of 9 units. 3) Not stated	management group with senior health manager for strategic development issues such as funding, training and legal issues. Draft protocols sent to 40 GP practices for consultation with 6 replies. Protocols modified and ratified by working party and project management groups. 6) Yes, identified best practice through discussion, gathering research evidence and visits to 2 nurse-led units.	with an algorithm to follow through a range of typical situations that would require decision making. On reverse was a standard format for gathering clinical and personal information and space for free text, similar to pre-existing documentation.
	22	J. Marshall, C. Edwards & M. Lambert (1997)	a) Nurse administration of drugs b) Protocol, clinical protocol c) Emergency Nurse Practitioners (ENPs) – three years full-time experience and course	a) Descriptive case study and audit b) Not stated c) Accident & Emergency Department in a District General Hospital d) Not stated e) No – developmental processes and audit	1) Role of ENPs to assess, diagnose, treat and advise patients within defined protocols. 1a) Enhance service if able to administer medication, reduce patient delays and the inappropriate use of doctors' time and to improve patient and staff satisfaction. 2) Working party formed. Protocols developed with the A&E consultants by the ENPs. 3) Not stated	4) Yes, to address legal and professional issues from nurse administration of drugs. 5) Discussions in A&E between ENPs, consultants and pharmacists to identify drugs. 5a) Working party recommendations submitted to Drugs and Therapeutics Committee and Trust Board. Trust solicitors consulted and accepted vicarious liability on behalf of nurses following the protocols. 6) Not stated	7) Not stated 8) Not stated

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	23	A. O'Cathain, F.C. Sampson, J.F.Munro, K.J. Thomas, J.P. Nicholl (2004)	a) To underpin a 24 hour telephone advice line staffed by nurses b) Computerised decision support software, standardised protocols, protocols, algorithms, guidelines, decision tree c) NHS Direct Nurses	a) Qualitative, semi structured interviews b) Not stated c) NHS Direct d) 24 NHS Direct Nurses in 12 sites e) Yes, views about role and impact of software on decision making	1) Reduce demand on out-of-hours GP services and A&E departments. 2) Not relevant as using 3 types of decision support software purchased for NHS Direct. 3) Not relevant - national procurement	4) Not relevant 5) Not relevant 6) Not relevant	7) Not relevant 8) Not relevant
	24	S. Partington (2003)	a) Protocol for the diagnosis and management of DVT in an outpatient setting b) Protocol c) Vascular nurse specialists	a) Descriptive case study b) Not stated c) Vascular Studies Unit, in a District General Hospital d) Not stated e) No – development as part of a new nurse-led service	1) Audit showing diverse diagnosis and treatment and therefore costs of DVT patients within the Trust. 1a) Change from in-patient to out-patient service. 2) Working group consisting of the vascular surgeon, vascular nurse specialists and the business manager. 3) Not stated	4) Used audit results to produce a business plan for Trust Board. 5) Protocol agreed after several months discussion in hospital and primary care settings. 5a) Approval inferred from receipt of extra funding for a duplex scanner and an extra vascular specialist nurse. 6) Collated information and research to devise protocol.	7) Not stated 8) Inferred from description of the protocol.
	25	H. Pinnock, G. Hoskins, B. Smith, T.	a) Promote use of evidence-based national	a) Pilot study with pre and post intervention audit	1) Acute asthma not managed in optimal way when measured against national guidelines.	4) Not stated 5) Inferred from recruitment to the pilot study.	7) Baseline data from 7 centres using a critical

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		Weller, D. Price (2003)	guidelines for management of acute asthma b) Management guidelines, proforma c) Nurses including 8 asthma trained nurses and doctors	b) Not stated c) 4 GP practices, 2 Out-of-Hours services and 2 nurse-run Walk-In Centres d) Not stated e) No – interventions to improve compliance with national guidelines	1a) Feasibility of using the General Practice Airways Group (GPIAG) Professional Development Programme which promotes organisational and personal development. 2) Not stated 3) Not stated	6) Data from baseline audit (see 7) feedback with comparative data from other primary care organisations.	event analysis of 160 acute asthmatic attacks over 3 months which suggested that guidelines not being fully adhered to. 8) Not stated
26		T. Porrett, C.H. Knowles & P.J. Lunniss (2003)	a) To facilitate role extension and nurse-led management of idiopathic anal fissure b) Protocol, treatment protocol, treatment pathway c) Nurse practitioners (NP) and surgical staff	a) Case study with an audit comparing NP and standard medical treatment by consultant or SpR b) 3 years, 1998-200 c) Outpatient colorectal clinic held in a District General Hospital d) 198 patients attending clinics with treatment outcomes for 135 e) No, patient outcomes and trialling a nurse-led clinic f) None cited	1) Accepted that common, benign coloproctological conditions can be managed by appropriately trained and supported nurse specialists. 1a) Busy, overbooked and late running clinics. Also to 'standardise' treatment and support surgical trainees. 2) No, stated plotted treatment pathway from audit and used key points from pathway to develop the protocol. 3) No. Produced a patient information leaflet.	4) Not stated 5) To enable role extension to be formalised documents for 'training', 'competency' and 'assessment' were reviewed. 5a) Ratified by Trust Policy review and Validation Group, the Drugs Committee and the Clinical Board. 6) Yes, protocol based on observations of current practice and by audit of use of Glyceryl Trinitrate	7) Not stated 6) Protocol included in article. 8a) Also report producing a document 'dispensing from within a protocol' to support nurse-led service.

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	27	W.P. Robson, S. Webster, K. Blakemore, M. Shepherd, J. Groves, T. Tague (2003)	a) To ensure prompt treatment of hypotension and allow nurses to administer fluid boluses. b) Patient Group Directive (PGD) c) Nurses, orthopaedic nurse practitioners	a) Detailed case study b) Not stated c) Critical Care Unit and outreach service in a District General Hospital d) Patients undergoing major orthopaedic surgery e) No, on the development of the PGD	1) To reduce risks of surgery. 1a) To help nurses identify high risk patients and be empowered to manage them. Reduced availability of junior doctors working fewer hours. Results of audit (see 7) 2) No, infer a consultative process in that the nurse consultant for critical care requested the Trust's Head of Pharmacy Services, produce an initial draft of the patient group direction. Draft refined in collaboration with nurse practitioners, critical care outreach team and supervising anaesthetist. 3) Not stated	4) Not stated 5a) Trust established standard template for PGDs with authorisation by medical and nursing staff and Trust's Drug and Therapeutics Committee. PGD approved by Trust Committee. 6) Not stated	7) Hospital audit showed a significant level of post-operative hypotension following major joint surgery. 8) Yes, protocol in the article.
	28	J. Smith & L. Callaghan (2001)	a) To allow children to be sedated safely and effectively. b) Clinical guidelines, structured sedation protocol, standards, checklist, formal protocol c) Multi-disciplinary	a) Descriptive case study and audit b) Not stated c) Children's Surgery ward in a Teaching Hospital d) Not stated e) No – details of development process and patient outcomes	1) Reduce diversity of practices when caring for children requiring sedation and the potential for a catastrophic event. 2) Core guideline development team comprised a paediatric anaesthetist, paediatric surgeon, radiologist and two experienced children's nurses; and 43 other staff were consulted. A working agreement was negotiated where the 5 core members had responsibility for writing the guidelines and feeding back to	4) Not stated 5) Yes, stated that hoped by involving many members of the multi disciplinary team throughout the process that this would aid in changing practice. Main disagreements about terminology rather than management and resolved by re-wording the guidelines. The guidelines were endorsed by the multi disciplinary team. 6a) Literature review undertaken by both authors	7) Not stated 8) Guideline stages summarised in article. 8a) Guidelines presented, with several sub-sections to allow quick referencing. Supporting strategies to implement the guidelines included formulating a checklist to be

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					the wider team. 3) No. Information sheets for parents developed as part of the implementation strategy.	using CRD, Cochrane, CINAHL, Medline and grey literature with findings outlined. Paucity of high quality research.	completed before sedation by medical staff and retained in case notes and also a core care plan.
	29	D. Thorpe & L. Harrison (2002)	a) Prevention and management of constipation in the critically ill b) Guidelines, protocol, flowchart c) Critical care nurse	a) Descriptive case study with a national survey of senior nurses on 100 ICUs literature review b) Not stated c) Critical Care Unit d) Not stated e) No, summary of findings that underpinned guideline	1) Discussion with colleagues indicated problem with constipation and also highlighted by patients during stay in an intensive care unit. 2) Not stated 3) Not stated	4) Not stated 5) Consulted with range of clinical experts when constructing guideline. 6) Survey of 100 randomly sampled ICUs in UK about bowel management. 17 (21%) had guideline or protocol. 6a) Literature review with search of CINHAL, Medline and DARE produced little research evidence to inform practice.	7) Not stated 8) Inferred from documentation. 8a) Guideline presented as a flowchart with supporting rationale for action. Included in the paper record and A4 laminated copies at each bedspace.
	30	V. Turner (1991)	a) Standardise nurses' approach to wound management b) Protocol, flowchart c) Student and qualified nurses	a) Descriptive case study b) Not stated c) Surgical orthopaedic ward d) Not stated e) No – about best evidence for wound healing and care	1) Improve wound care knowledge and management. 1a) To encourage nurses to comply with the research evidence, to teach a problem-solving approach to wound care and bring their knowledge to attention of doctors. 2) No, devised by ward sister 3) Not stated	4) Not stated 5) Not stated 6) Yes, choice of dressings based on published research and practical experience	7) Not stated 8) Yes, flowchart include in the article.

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	31	M. Wainwright, S. Fishburn, N. Tudor-Williams, H. Naoum & V. Garner (2003)	a) To improve consistency of diagnosis and treatment of women with symphysis pubis dysfunction (SPD) b) Guidelines, protocol, care pathways, flow chart c) Midwives and multi-disciplinary team	a) Detailed case study with pre-audit data b) Not stated c) Maternity care in primary and secondary care settings d) Women with SPD e) No, responding to need and developing the protocol	1) Audit conducted in response to local SPD support group noting increased number of contacts (see 6). 1a) Concerns about longer term problems from SPD. 2) Multi-disciplinary protocol development group established on recommendation of MSLC. Group chaired by officer from the Community Health Council and consisted of service user, physiotherapist, practice development midwife, manager, obstetric consultant and specialist nurse in disabilities. 3) Instigated by patient representative support group. Users on the development group. Produced two advice leaflets for women.	4) Yes, to make sure all patients receive appropriate, timely interventions; to bridge professional roles and agency boundaries and raise awareness. 5) Implied from survey and support of MSLC. 6) Postal questionnaire sent by support group to 31 women found delays in diagnosis, poor communication, disparity in treatment and advice and difficulty accessing treatment. Finding presented to Maternity Service Liaison Committee (MSLC).	7) Yes, support group postal survey of women (see 6). 8) Yes, guideline included in article. Reported generating a care pathway to identify 'glitches' in care system. 8a) Described using existing information eg health promotion page from hospital booklet, adding to antenatal care guidelines and revising intrapartum guidelines.
	32	C. Wardman (2002)	a) Support development of advanced practice, nurse-led fracture review clinic b) Injury specific protocols, flow charts c) Nurse practitioners	a) Case study with audit and patient satisfaction survey. b) Not stated c) Nurse-led fracture review clinic in an Orthopaedic Outpatients Depts. d) Patients with distal radial fractures, e) No – description of the process	1) Improve quality of care, reduce waiting times and increase patient information by developing in a new service. 2) Not stated. The consultant decided the type of injury with predictable outcomes to be seen at the review clinic. 3) Not stated	4) Yes, aims of project and learning outcomes (knowledge and skills) 5) Not stated 6) Brief audit of activity in plaster room suggested that 35% (N=47) had injuries that could be treated by injury specific protocols within a nurse-led service. 6a) Systematic literature review was conducted which	7) Yes, see 6 re audit. 8) Existing medical protocols used as guidance for nurse-led protocol. 8a) Database developed to provide accurate record of activity in the service.

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			(N=3)			highlighted variety of titles and role of nurse practitioners, safe practice, autonomy and risk management.	
33		C. Wood (2002)	a) Injection protocol to reduce pain and distress levels reported by children. b) Protocol c) Paediatric nurses	a) Quasi experimental audit with treatment and control group using a self-report questionnaire b) Not stated c) Paediatric Unit and A&E phlebotomy d) 82 children between 6-16 years e) No – patient outcomes	1) Assess, prepare and distract children from pain during cannulation. 1a) Develop a standard for venepuncture – cannulation and reduce need for restraint. 2) No, protocol formulated in conjunction with the child psychologist. 3) No, parent advice and information leaflet about the procedure.	4) Yes. Study defined as an audit by the hospital research department. 5) Not stated 6) Not stated	7) Not stated 8) Yes, protocol content - instructions and guidance described in the article.

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Appendix 2c: Table of findings : Implementation

Table 2.5. Implementation - details about 33 included UK papers using the 12-steps and additional ones derived from data (a/b)

Table 2.5	Ref ID	Authors Publication year	a) Protocol aim b) Terms used a) Protocol users	a) Study design b) Study duration c) Study setting d) Population e) Primary focus on staff?	9) Pilot the protocol 9a) Evaluate 9b) Training	10) Implementation 10a) Dissemination	11) Monitor variation 11a) Compliance 12) Review the protocol
	1	Ayris (2002)	a) Permit the verification of expected, out-of-hours death at home by district nurses b) Procedures, protocol c) Registered nurses on the out-of-hours district nursing team	a) Descriptive case study b) Not stated c) Primary care d) Not stated a) No – development process	9) not stated 9b) Multi disciplinary, post graduate accredited evening meeting with invited speakers to discuss to initiative, was attended by GPs, nurses and funeral directors. Training programme offered to first-level registered nurses which included discussion of the protocol, role and skills required, accountability and legal issues. Only nurses who had undergone training able to formally verify death and remove any syringe drivers.	10) Yes, decision to implement with an accompanying training package.	11) Not stated 12) Used for three months and no negative feedback. '*Nurses involved all felt that they now provide a much improved service to the relatives. Informal feedback from the relatives has been positive*.' (p373). Protocol to be reviewed on an annual basis. Local university now offering training in this area for community nurses and nurses working in care homes.

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	2.	Baird, Henry, Liddell, Mitchell & Sneddon (2001)	a) To overcome an infection control problem b) Protocols, policies, procedures, integrated care pathway, care pathway protocols, checklist c) Multi disciplinary team	a) Descriptive case study b) Not stated c) Ophthalmology Unit d) Not stated e) No, description of application of hazard analysis critical control points (HACCP)	9) Not stated	10) Project team recommended changes in surgical procedures, managerial control and incorporate changes in care pathways into patient information leaflet.	11) Not stated 12) State currently being audited and 'throughout the exercise … staff have been empowered to improve control of the patient care pathway' (p20).
	3	Bell, Solieri, West, Burgess & Dowdeswell (1997)	a) Standardise nursing care throughout hospital of patients with fractured neck of femur b) Nursing protocol, clinical care protocol c) Nurses	b) Case study with pre and post design c) Two years d) Hospital e) Fractured neck of femur (N=700) f) Yes – outlined process and benefits for nurses	9) Not stated	10) Pre and post implementation data about pressure sores, blood tests and number of wards patients allocated to. Descriptions of A&E nurse protocol, orthopaedic nurse protocol, post-operative period and rehabilitation.	11) Not stated 12) Not stated

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	4	Birchall, Street & Clift (2002)	a) Develop a Trust wide approach to use of Topical Negative Pressure (TNP) for wound healing b) Protocol, procedure c) Nurses	a) Descriptive case study b) 11 months c) Two hospitals d) Not stated e) No – developing a Trust wide policy	9) Stated that no pilot was undertaken. 9b) Yes, formal and informal education sessions to support the protocol with members of the working party speaking at Trust wide good-practice days and a study afternoon; also training on a one-to-one basis in clinical practice. TNP included in introductory sessions about the tissue viability service. Training also provided for multidisciplinary team in burns and plastic surgery unit. Two nurses completed competency-based assessment after first 6 months.	10) Yes, Trust wide approach introduced and protocol included in Trust's wound dressing guide.	11) Not stated 12) Evaluation of the cost implications and patient use 6 months after the introduction.
	5	Bowman (2000)	a) Expanding role and introducing nurse prescribing b) Treatment protocols, protocol nurse prescribing c) Dermatology nursing team	a) Descriptive case study b) Not stated c) Nurse-led and administered day care dermatology unit with consultant supervision d) Not stated e) No – development of unit and nurse prescribing	9) Not stated 9a) Audit of 47 sequential patients out of 200 when unit opened to evaluate safety of nurse prescribing; and patient satisfaction questionnaire.	10) Inferred from audit.	11) Not stated 12) Audit revealed abuse (repeat prescriptions) and new form designed and approved.

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	6	Bruton & McPherson (2004)	a) To improve weaning of ventilated patients b) Protocols, structured protocol-driven approach, flow chart. c) All staff on ICU	a) Descriptive case study with some pre and post protocol data about staff perceptions b) Not stated – year before protocol embedded in practice c) General Intensive Care Unit in a Regional General Hospital d) Not stated e) Yes – part of setting up a multi disciplinary weaning team	9) Not stated 9a) Audited patient outcomes - rate of reintubation decreased. 9b) Yes, rolling education programme to inform about evidence, need to change practice and seek views. Also practical demonstration by senior physiotherapist to all staff on all shifts during first few weeks. Continued education of all staff –reassurance about delegated decision making for junior staff (see 11).	10) Indirectly, barriers to change are discussed. 10a) Results of audit disseminated by posters, written report, oral presentations and report at meetings.	11a) Indirectly, commented about piecemeal adoption by some consultants. Varying skills mix amongst nursing staff, some junior staff not comfortable with perceived increase in responsibility and screening criteria seen as 'optional extra' especially at weekends. 12) Yes, staff questionnaire and patient outcomes.

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	7	Carr, Lhussier & Wilcockson (2005)	a) Study comparing two approaches to service / practice development: introducing the Liverpool end of life care pathway b) Integrated care pathway c) Community nursing staff and general practitioners	a) Comparative case study with interviews (N=32) b) 18 month implementation period c) 2 Primary Care Trusts d) Not stated e) Yes, transfer of knowledge from specialists to generalists	9) Not relevant 9b) Site with 'buy in' of expert time included extensive generic education sessions with hospital ward and primary care staff prior to introduction by clinical nurse specialists which covered barriers to implementation ie workload, time and 'cookbook medicine.' Both sites – Multi-disciplinary education and reflection with group review and education sessions were offered by the Clinical Nurse Specialists. Also early introducers became mentors for those using the LCP later in the scheme.	10) Site with 'buy in' of expert time - chronology described as incremental and by self-selection. Site buying out generalist time – phased introduction and self-selecting primary health care teams with funding to provide back-fill for staff participation.	11) Not stated 11a) Use evidenced by seeking advice about the LCP from colleagues. 12) Not stated

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	8	Christensen (2002)	a) Enable nursing staff to facilitate nurse-led chest drain removal independently of medical staff input b) Working standard, algorithmic model c) Suitably qualified 'E' and 'F' grade nursing staff ie completed the Entonox study day and been assessed as competent	a) Case study with a pilot b) Not stated c) Cardiac high dependency unit d) Uncomplicated 'fast track' elective cardiac surgery patients. e) No – process of development	9) Pilot with 50 post cardiac surgery patients to ascertain workability of the standard. Only 2 (4%) had drain removed independently by nurses. Following feedback, algorithm was refined and a second pilot study done with 50 patients with 56% having drains removed independently and without any complications. 9a) Used 15 item audit tool devised by steering group with advice from clinical effectiveness team 9b) Informal teaching sessions to address concerns about the algorithm decision-making tool prior to the pilot.	10) Not stated	11) Not stated 12) Need for further evaluation and clinical audit reported.
	9	Clark, Day, Howe, Williams & Biley (1995)	a) Improve the immunisation uptake rate b) Protocol c) Health visitors	a) Descriptive case study b) Protocol developed over 12 months c) Health Visitor Development Unit in a Fund holding GP Practice d) Practice population e) No – part of project to improve immunisation	9) Three month pilot study involving 23 children. 9b) Yes – up dating educational programme about safe handling of vaccines for health visitors. Training in basic computer skills. Studied training package about informing parents. Assessment of competence in clinical setting by Community Medical Officer.	10) No, inferred – immunisation rate increased to over 90% and Practice achieving target payments.	11) Not stated 12) Not stated

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	10	Davies (1996)	a) Improve the assessment and treatment of chronic leg ulcers b) Protocol, standard management protocol, guidelines c) Community nurses	f) Descriptive case study and audit g) Not stated h) Primary Care i) Patients with leg ulcers j) No – development and audit	9) Not stated 9a) Final assessment conducted three months after management plan agreed (see 7). 9b) Some nurses trained to take Doppler measurements and apply high compression bandages and cellulose packing.	10) Not stated – inferred (see 7.)	11) Results about prevalence and healing of leg ulcers and average time nurses spent with patients: reduced from average 647 minutes per patient to 359 minutes 12) Working party recommended that the protocol should be monitored regularly by audit.
	11	Davis, Bowman & Shepherd (2004)	a) Facilitate a fast track protocol-directed nurse-led iron deficiency anaemia (IDA) clinic b) Protocol, clerking sheet c) Nurse specialist (N=1)	a) Case study evaluation b) 15 months c) Outpatient clinic d) First 100 patients referred to clinic e) No – patient outcomes	9) Not stated 9b) Nurse had attended the consultant clinic, observed and been taught basic examination for a three month period.	10) Clinic run in parallel with gastroenterology out patient clinic and all patients discussed with consultant or specialist registrar and a management plan decided upon.	11) Yes, all patients seen within target time and 80% malignant disease diagnosed within 3 weeks. 12) Not stated

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	12	Dibb, Fawcett & Whall (1999)	a) Nurse-led pre operative optimisation to improve patient outcomes. b) Standardised protocol, flow diagram, guidelines c) Senior nurses: 5 years ICU experience, research qualification and ICU course	a) Descriptive case study b) Intensive Care Unit and High Dependency Unit c) District General Hospital d) High risk of peri-operative complications following major abdominal elective surgery e) No, development of protocol used in an RCT	9) Not stated	10) Yes, stated administered protocol using their knowledge, skill and expertise so as to be responsible to individual patient need.	11) Not stated 12) Stated being developed for use as general policy on ICU and HDU.
	13	Forbes, Berry, While, Hitman, Sinclair (2004)	a) Explore feasibility of district nurse led annual diabetes review b) Protocol, guidelines, treatment pathway c) District Nurses (DN) (N=4)	a) Pilot study with pre/post design with patient questionnaire, DN interviews and time log b) 6 months c) GP practices d) 12 frail older people with type 2 diabetes e) No – impact on patients and cost	9) A pilot study 9b) Nurses trained in administration of the protocol. Evaluated as sufficient for the annual review but would have liked extra training in foot and eye assessment.	10) Inferred from audit findings.	11) Research nurse attended each assessment to ensure consistent protocol adherence. 12) Not stated
	14	Haw & Kitching (2000)	a) Structure care for patients with healed venous leg ulcers b) Care protocol, protocol for patient-led care c) District nurses	a) Descriptive case study with pre/post audit b) Not stated c) Not stated d) District nursing team e) No, description of development process	9) Not stated 9b) Education of patients.	10) Inferred from case load audit results (see 11) and statement that protocol is '*well integrated into everyday practice*' (p38).	11) Recurrence rates reduced from 51% in 1997/1998 to 40% in 1998/1999. 12) Not stated

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	15	Jeffery (2005)	a) To standardise practice in screening patients with Barrett's oesophagus b) Protocol, local guidelines c) Nurse endoscopist practitioner (N=1)	a) Descriptive case study and pre audit b) Not stated c) Nurse-led clinic in an endoscopy unit d) Not stated e) No, development of the protocol	9) Not stated	10) Yes, described establishment of a nurse-led clinic to manage Barrrett's patients with the nurse endoscopist using the protocol. Clinic, set up for 3 months and runs alongside a consultant gastroenterologist clinic who is consulted if advice is required.	11) Not stated 12) States will conduct an audit and formally assess patient satisfaction.
	16	Johnson, Griffiths & Birch (2003)	a) Nurse prescription of topical glaucoma medication b) Protocol, flow pathway, written protocol c) Experienced E & F grade ophthalmic staff nurses (N=3)	a) Case study and audit b) 12 months c) Nurse-led glaucoma triage assessment clinic d) All patients referred with suspected glaucoma, except those with difficult diagnosis. e) No – new service and patient outcomes	9) Yes, reporting a pilot scheme with medical staff checking nurses' decision before prescribing. 9a) Two audits: all patients (N=169) attending for two periods and all (n=52) patients attending and started on treatment by nurses over a 12 month period. Audit of diagnostic accuracy after three months. 9b) Specific training in optic disc assessment, seeing patients in parallel with consultant until felt to be of an appropriate standard.	10) Yes, detailed audit findings in the article.	11) Yes, from audit. Nurses unable to categorise 4 patients according to protocol. 12) Not stated

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	17	Johnston (2006)	a) To set a multi-disciplinary, explicit standard and record of care b) Integrated care pathway (ICP), local guidelines c) Multi-disciplinary team	a) Descriptive case study with audit and observation of nurses hand-over at 6 shift changes on the stroke unit b) Not stated c) Stroke rehabilitation unit and acute medical wards d) Stroke patients e) Yes – adequacy of, and use of ICP documentation	9) Not stated 9a) Audit to compare nurses spoken information and that written information on the ICP at shift handover.	10) Not stated	11a) 25% of verbal statement at handover not written on ICP. 12) Not stated
	18	Kilburn (2002)	a) Develop nurse practitioner role to carry out procedure - flexible cystoscopy- beyond scope of practice b) Protocol c) Urology nurse practitioner and doctors	a) Descriptive case study b) Not stated c) Day case unit in a Hospital d) Not stated e) No – development of nurse-led service	9) Not stated 9b) 'In house' training using Guidelines for Nurse Cystoscopists (BAUS 2000).	10) Inferred from audit of protocol one year after introduction.	11) Not stated 11a) Retrospective audit of 60 case notes from 7 month period. Found that 25 (42%) did not comply with the protocol. 12) Resulted in re-wording the document and reinforcing treatment patterns so protocol easier to follow. Protocol re-audited using same method one year after implementation with 98% compliance.

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	19	Kinley & Brennan (2004)	a) Encourage a consistent approach to oral care in one palliative care unit b) Protocol, standard, protocol of care c) d) Palliative care nurses	a) Case study with a survey of knowledge and practice and retrospective audit b) Not stated c) 12 bed, in patient palliative care unit d) Not stated e) No – development process and audit	9) Not stated 9b) Results of survey of knowledge used to prepare an educational programme. This included refresher training for all staff comprising feedback on the audit, demonstration of oral care and a video, given by a multidisciplinary team from the hospital and university. Second knowledge survey distributed post implementation which showed less variation in practice and increased awareness of good mouth care. Recommended continuing the refresher sessions and including in staff induction.	10) Yes, implemented with the documentation and educational programme.	11) Retrospective audit of medical and nursing notes and care plans of all patients (N=47) three months post implementation. Nursing assessment of mouth care improved from 28% to 96%. *'By sharing best practice it appeared that the nursing team had been empowered to change their practice'* (p585).

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	19						12) Documentation – mouth care plan revised following audit. Project extended to 4 pilot wards – surgery, medicine, ICU and care of the older person – using similar process with the addition of training manual for each ward - and findings. Now used across the Trust and being introduced into the Primary Care Trust.
	20	Laver, Preston, Turner, McKinstry & Padkin (2004)	a) Prescriptive intravenous insulin infusion protocol to control blood glucose b) Protocol, Bath Insulin Protocol c) Intensive care nurses	a) Descriptive case study with pre and post audit b) 6 months c) Intensive Care Unit in a District General Hospital d) Medical and surgical intensive and high dependency patients e) No – impact on patient outcomes	9) Not stated 9a) Audit during development: protocol was used on 79 patients - maximum of 2 patients concurrently - to monitor safety and effectiveness. Audit of first month of routine use by retrospective chart review and compared with same month a year earlier.	10) Yes, routine use of the optimised final protocol audited after first month.	11) Not stated 11a) Audit of first month found that only 56% eligible patients started on insulin. 12) Not stated

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	21	Macduff, West, Lawton, Leslie & Ironside (2001)	a) Facilitated development of nurse-led treatment for minor injuries b) Protocol, assessment and treatment protocols, flow chart, algorithm c) Senior casualty nurses and GPs	a) Case study and baseline audit b) Not stated c) Casualty Units in 9 Community hospitals d) Not stated e) No – description of development and audit	9) Protocols piloted in early 1997 which showed variation in documentation. Monthly meetings to discuss teething problems with format and differences in interpretation until standard approach to completion agreed in January 1998. 9a) Strategy for auditing the new protocols was developed so that subsequent progress across the 9 units could be measured from a common baseline standard. 9b) A short skills-based educational programme created, ran concurrently with the pilot and was completed by 88 of senior casualty nurses during 1997.	10) Protocols introduced in all 9 units by autumn 1997.	11) Audit in June 1998 of 20 randomly selected cases from each unit which revealed wide variation in completing the protocol and quality of the information. Findings fed back to each unit and to the working party. Problems included design of the form,

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	21						multiple protocols inducing unnecessary duplication, protocol flow charts options not fitting exactly patient's injury or being mutually exclusive. Reasons were differences in communication, ownership and management of change in each unit. 12) Yes, layout changed and framework for units to conduct own audits. Also exploring using computers to aid decision making processes.
	22	Marshall, Edwards & Lambert (1997)	a) Nurse administration of drugs b) Protocol, clinical protocol c) Emergency Nurse Practitioners (ENPs) – three years full-time experience and course	a) Descriptive case study and audit b) Not stated c) Accident & Emergency Department in a District General Hospital d) Not stated e) No – developmental processes and audit	9) Not stated 9a) General audit of 1 in 10 of ENP cases in first 6 months with (N=455) and audit of specific drugs (tetanus and post-coital contraception). 9b) Additional training - 6 ENPs attended a study day- to be accredited by Trust to give drugs and to be acceptable to A&E consultants.	10) Inferred from audit and annual review	11) Audit revealed '*no breaches of the protocols*' (p235). 11a) Yes, 94-100% compliance with immunisation and 71-100% with contraception. 12) Reported minor changes to clarify protocol following the audits. Annual review of protocols and further study day with re-accreditation.

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	23	O'Cathain, Sampson, Munro, Thomas, Nicholl (2004)	a) To underpin a 24 hour telephone advice line staffed by nurses b) Computerised decision support software, standardised protocols, protocols, algorithms, guidelines, decision tree c) NHS Direct Nurses	a) Qualitative, semi structured interviews b) Not stated c) NHS Direct d) 24 NHS Direct Nurses in 12 sites e) Yes, views about role and impact of software on decision making	9) Not relevant as a national system	10) Software described as a 'safety net', provider of consistency and a script but insufficient; needed to consider and interpret contextual and other relevant information. Use dual triage with the software as a tool, prompt or support with the nurse's critical thinking and making the clinical decision by over riding or internalising the software.	11) Yes, management policies about requirement that nurses use the software, but they navigated the software to produce most appropriate recommendations 12) Not relevant
	24	Partington (2003)	a) Protocol for the diagnosis and management of DVT in an outpatient setting b) Protocol c) Vascular nurse specialists	a) Descriptive case study b) Not stated c) Vascular Studies Unit, in a District General Hospital d) Not stated e) No – development as part of a new nurse-led service	9) Not stated	10) Yes, from Nov 2001 all patients with suspected DVT managed according to agreed protocols.	11) Not stated 11a) Number of scans preformed and reduction in bed occupancy. 12) Yes, service continues to be audited and continual monitoring of the protocol.

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	25	Pinnock, Hoskins, Smith, Weller, Price (2003)	a) Promote use of evidence-based national guidelines for management of acute asthma b) Management guidelines, proforma c) Nurses including 8 asthma trained nurses and doctors	a) Pilot study with pre and post intervention audit b) Not stated c) 4 GP practices, 2 Out-of-Hours services and 2 nurse-run Walk-In Centres d) Not stated e) No – interventions to improve compliance with national guidelines	9) Evaluation of the pilot study using baseline date (see 7), then intervention and follow-up questionnaire about service provision and interventions. Intervention included feed back on baseline data; symposium at a National Congress which facilitated multi-disciplinary discussion; provided with list of references, resources and practical materials; post Congress 'progress form' with own developmental plans. 9b) Stated that the national Congress 'probably not ideal venue for the educational intervention – 50% non-attendance.	10) All organisations received the resource pack. Three practices received customised feedback from baseline audit data. Three GPs attended the Congress. Stated that '*there were problems for the larger organisations, in implementing change within the six-month timescale*' (p11). 10a) Strategies for change included development of proforma for call handlers to prompt the recording of assessment and appropriate action; and patient group direction to allow nurses to administer prednisolone.	11) Five organisations completed follow-up data questionnaire. 12) Not appropriate as a national guideline.

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	26	Porrett, Knowles & Lunniss (2003)	a) To facilitate role extension and nurse-led management of idiopathic anal fissure b) Protocol, treatment protocol, treatment pathway c) Nurse practitioners (NP) and surgical staff	a) Case study with an audit comparing NP and standard medical treatment by consultant or SpR b) 3 years, 1998-200 c) Outpatient colorectal clinic held in a District General Hospital d) 198 patients attending clinics with treatment outcomes for 135 e) No, patient outcomes and trialling a nurse-led clinic	9) Protocol developed from observation of current practice. 9b) NP observed Consultant-led consultations and *with sufficient experience, the NP then reviewed (at the same appointment) by the Consultant. Once assessed as competent by the Consultant, the NP saw patients independently (with the Consultant available if necessary)'* (p64).	10) Yes, results of the audit	11) Yes, pilot comparing patient outcomes – fissure healing rates and patient compliance. 12) Yes, possible to adapt to future treatment developments and appointment of a Nurse Consultant for a nurse-led clinic where the *'treatment protocol is followed and … if the nurse has any concerns the patient is referred directly into the Consultant clinic … this new initiative is being closely audited'* (p67).
	27	Robson, Webster, Blakemore, Shepherd, Groves, Tague & Stevens (2003)	a) To ensure prompt treatment of hypotension and allow nurses to administer fluid boluses. b) Patient Group Directive (PGD) c) Nurses, orthopaedic nurse practitioners	a) Detailed case study b) Three months c) Critical Care Unit and outreach service in a District General Hospital d) 14 Patients undergoing major orthopaedic surgery e) No, on the development of the PGD	9) PGD piloted over a three month period. 9a) Audit with 14 patients over a 3 month period with patient outcomes that showed that *'allowing nurses to give fluid boluses for hypotension was safe and effective'* (p200).	10) Inferred from pilot.	11) Not stated 12) Suggest extending to PGD to pre operative patients and other post operative patients.

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	28	Smith & Callaghan (2001)	d) To allow children to be sedated safely and effectively. e) Clinical guidelines, structured sedation protocol, standards, checklist, formal protocol f) Multi-disciplinary	f) Descriptive case study and audit g) Not stated h) Children's Surgery ward in a Teaching Hospital i) Not stated j) No – details of development process and patient outcomes	9) Not stated 9a) Audit criteria and documentation (incorporating the standards into a checklist) developed as part of the implementation strategy. 9b) Staff training sessions part of the implementation strategy.	10a) Supporting strategies to implement the guidelines included documentation (see 8a), dissemination through child health committee, presentations at children's service nursing meetings, and a high profile campaign to raise awareness through posters.	11) Results from 88 cases audited with 95% successful sedations. 90% of omissions related to standard about explaining procedure to carer and obtaining consent. 12) Not stated
	29	Thorpe & Harrison (2002)	a) Prevention and management of constipation in the critically ill b) Guidelines, protocol, flowchart c) Critical care nurse	a) Descriptive case study with a national survey of senior nurses on 100 ICUs literature review b) Not stated c) Critical Care Unit d) Not stated e) No, summary of findings that underpinned guideline	9) Not stated 9b) Provided interactive training sessions to multi disciplinary team members when had opportunity to refine the guideline. Display on notice board and literature review and articles available in resource room.	10) Yes, refer to difficulties associated with the management of change and need to disseminate widely. Identified key staff members to support dissemination and promote the guideline. 10a) A4 laminated copies given to all nursing and consultant medical staff.	11) Not stated. 12) Not stated.

The Contribution of nurses, midwives, and health visitors to protocol-based care and its variants,
and the impact of their contribution on patient and staff outcomes, quality and costs of care

(SDO Project 08/1405/079)

Table 2.5	Ref ID Publication year	Authors	a) Protocol aim b) Terms used a) Protocol users	a) Study design b) Study duration c) Study setting d) Population e) Primary focus on staff?	9) Pilot the protocol 9a) Evaluate 9b) Training	10) Implementation 10a) Dissemination	11) Monitor variation 11a) Compliance 12) Review the protocol
	30	Turner (1991)	a) Standardise nurses' approach to wound management b) Protocol, flowchart c) Student and qualified nurses	a) Descriptive case study b) Not stated c) Surgical orthopaedic ward d) Not stated e) No – about best evidence for wound healing and care	9) Not stated 9b) Inferred training from description of questions to ask about wound care.	10) Inferred from statement about review over four years.	11) Not stated 12) Yes, stated been subject to regular review and updating.
	31	Wainwright, Fishburn, Tudor-Williams, Naoum & Garner (2003)	a) To improve consistency of diagnosis and treatment of women with symphysis pubis dysfunction (SPD) b) Guidelines, protocol, care pathways, flow chart c) Midwives and multi-disciplinary team	a) Detailed case study with pre-audit data b) Not stated c) Maternity care in primary and secondary care settings d) Women with SPD e) No, responding to need and developing the protocol	9) Not stated 9b) Development group generated a multi professional education strategy across Trusts in county. Protocol was presented to service users, support staff, students, midwives, physiotherapists, consultants and general practitioners.	10) Yes, reported 'since introduction.'	11) Noted number of enquires to support group with reduced complaints. Author note that variations in practice between staff and different parts of the county had been observed. 12) Yes, state next stage is to audit the new pathway and review the content.

The Contribution of nurses, midwives, and health visitors to protocol-based care and its variants, and the impact of their contribution on patient and staff outcomes, quality and costs of care

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Table 2.5	Ref ID	Authors Publication year	a) Protocol aim b) Terms used a) Protocol users	a) Study design b) Study duration c) Study setting d) Population e) Primary focus on staff?	9) Pilot the protocol 9a) Evaluate 9b) Training	10) Implementation 10a) Dissemination	11) Monitor variation 11a) Compliance 12) Review the protocol
	32	Wardman (2002)	a) Support development of advanced practice, nurse-led fracture review clinic b) Injury specific protocols, flow charts c) Nurse practitioners (N=3)	a) Case study with audit and patient satisfaction survey. b) Not stated c) Nurse-led fracture review clinic in an Orthopaedic Outpatients Depts. d) Patients with distal radial fractures, e) No – description of the process	9) Not stated 9b) Educational framework established and approved by Advanced Practice advisory group. During the six month period the theoretical content was delivered by medical and nursing staff from Trust and University. Orthopaedic surgeon was the formal assessor in the clinic setting.	10) Yes, clinic runs one morning a week and is delivered concurrently alongside a Consultant clinic.	11) Initial audit 65% seen within appointed time. 12) Patient satisfaction questionnaire 42.2% response with 100% saying would see nurse again.
	33	Wood (2002)	a) Injection protocol to reduce pain and distress levels reported by children. b) Protocol c) Paediatric nurses	a) Quasi experimental audit with treatment and control group using a self-report questionnaire b) Not stated c) Paediatric Unit and A&E phlebotomy d) 82 children between 6-16 years e) No – patient outcomes	9) Not stated	10) Yes, 41 children in the treatment arm (injection protocol and parent information leaflet). Protocol set a standard that doctors should attempt cannulation twice and become better at doing so. Nurses became more confident in insisting that the doctors abide by the standard.	11) Not stated 12) Yes, children reported higher levels of anxiety and pain in treatment arm.

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NB 1-33 UK papers appraised in details using the 12 step framework

Appendix 2e: Introduction: impact

This section contains the findings from the systematic literature review to identify evidence about the ways in which standardised care impacts on the working lives of nurses, midwives and health visitors.

Sixty four papers were data extracted and outcomes grouped in to eight broad categories. The full methodology is describe in appendix 2a
In this appendix:

- Table 2.6 presents the categorisation of outcome data.

- Table 2.7 presents data from the papers on the impact of standardised care on nurses, midwives and health visitors.

References for this review are presented in appendix 2g

Impact outcomes measured in the research

In total 28 types of outcome were identified in the 64 papers. These were broadly classified in the eight main impact categories as indicated in table 2.6.

Table 2.6. Impact outcomes measured in the research

Impact Category	Impacts on Nursing Staff
Team working	Improved team working Improved communication Increased collaboration Increased awareness of roles of others
Expanded nursing roles	Expanded nursing role/responsibility Increased proactivity
Clinical freedom	Increased autonomy Empowerment Constrained use of own knowledge/experience
Job satisfaction	Increased satisfaction Increased confidence Increased commitment Improved morale More positive attitudes
Stress	Reduced stress Increased role clarity Reduced role conflict Reduced role overload
Patient care and understanding	Better understanding of patients Better communication with patients Increased motivation to care for patients Reduced quality of nursing as more protocols available
Clinical knowledge	Increased clinical knowledge More informed about overall care process
Clinical skills	Increased skills & abilities Deskilled nursing role Restricted decision making

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Appendix 2f: Table of findings: Impact

Table 2.7. Impact – details about 64 included papers

Table 2.7	Ref ID	Authors Publication Year	a) Protocol aim b) Terms used	a) Study design b) Study duration c) Study setting d) Country	a) Population b) Protocol users c) Primary focus on staff?	a) Protocol impact on staff – positive or negative b) Impact category c) Specific protocol impacts on staff	Study outcomes	a) Outcome measures used b) Validated/ reliable scales? c) Staff impact data reported?
	1	E. Alexander, F. A. Carnevale & S. Razack (2002)	a) To delegate decision making concerning sedation & analgesics to nursing staff b) Protocol	a) Post protocol b) Not stated c) Paediatric intensive care unit d) USA	a) Critically ill, intubated children (N=10) b) Nurses (N=53) c) No	a) Positive b) Improved team working Expanded nursing roles c) Improved patient care & understanding More effective management of patient comfort More efficient & rapid intervention Team decision-makingfacilitatedactive model that emphasises planning & anticipating patients' needs	Questionnaire – value of protocol – fellows & doctors, 53 returned Proactive/planning – reduces negotiation – goals already established (p298) Facilitated team decision making (p298). Data collected from charts & nursing records daily – patients receive more sedation on protocols Difference in views of doctors regarding regular use & over sedation	a) Questionnaire - staff perceived value of protocol, 5 point scale (ease of use, perceived safety, effectiveness, efficiency in reducing discomfort) b) Post protocol c) No d) No
	2.	B. J. Anderson, M. A. Persson & M. Anderson (1999)	a) To standardise the prescribing of	a) Post protocol b) Not stated c) Surgical ward, Auckland Children's Hospital	a) Child surgery patients (N=97 pre protocol, N=65 post protocol)	a) Positive b) Increased job satisfaction; Improved patient care & understanding c) High satisfaction with	There was no difference between the mean daily doses of morphine administration before	a) Questionnaire – nurse satisfaction Post protocol (6 months after implementation) b) No

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			morphine b) Protocol	d) New Zealand	b) Nurses (N=20) c) Yes	protocol for all nurses after 6 months Confidence assessing children's pain Improved understanding of children's pain & its management	(not nurse administered) and after the introduction of the protocol. Nurses reported a high level of satisfaction with the protocol at the 6 month review. Nursing staff reported confidence in assessing children's pain (p64)	c) Data – basic
	3	M. J. Bakker, P. D. Mullen, H. de Vries & G. van Breukelen (2003)	a) To improve smoking cessation and relapse prevention for pregnant women b) Protocol	a) Post protocol b) Not stated c) General Practice - antenatal care d) Netherlands	a) Pregnant women (N=556) b) Midwives (N=39 in intervention group, N=32 in control group) c) Yes	a) Positive b) Improved patient care & understanding c) Midwives who received training in the protocol were more likely to give advice to quit, set a date to quit & discuss care. Improved ability to help clients	Smoking behaviour of clients Clients in the experimental groups reported more often receiving info to quit.	a) Self designed questionnaire Post protocol b) No c) Data & stats

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	4	L. Bell, A. Solieri, P. West, K. Burgess & T. Dowdeswell (1997)	a) To coordinate care from A & E to discharge through nursing protocols for patients with fractured hips b) Protocol	a) Pre & post protocol b) Not stated c) Hospital d) UK	a) Patients with fractured neck of femur b) Nurses c) Yes	a) Positive b) Improved team working; Expanded nursing roles; Increased clinical freedom; Increased job satisfaction; Reduced stress; Improved patient care & understanding; Increased clinical knowledge Nurses more certain of their roles & responsibilities; Supported by protocols in care planning – revolves around key issues of good practice; Increased knowledge & communication – inform patients of exactly what to expect during stay; More aware of what support to expect from colleagues; Increased responsibilities – taking an overview, considering the patient as a person with their own needs; More informed about overall process of care; Increased nurse morale - feel they are giving a better quality of care; Empowerment – nurses responsible for specific aspects of care	Pre & post protocol audit data on patient outcomes More certain of their roles & responsibilities – A & E nurses & orthopaedic nurses (p1083) Inform patients regarding expectations, responsible for taking an overview of patients (p1084) Increased morale Feel empowered Use of standardised pressure sore measure Words but no data really	a) Audit Pre & post protocol b) No c) No

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	5	J. Bornman, E. Alant & L. L. Lloyd (2004)	a) To increase nurses' skills – multi-skilling b) Protocol	a) Pre & post protocol b) Not stated c) Community, North West Province d) USA	a) Children with severe learning difficulties b) Primary health care nurses (N=20) c) Yes	a) Positive b) Increased clinical freedom Increased job satisfaction Improved patient care & understanding Increased clinical knowledge Increased clinical skills Multi skilling training had a significant impact on nurses' acquisition of knowledge & skills; Increased awareness of importance of showing care givers how to communicate, of follow up services, of advice that could be given; Increased empowerment & confidence	Nurses were aware of importance of showing care givers how to communicate Nurses were aware of specific skills required Nurses were aware of types of advice that could be given	a) Observed demonstrations of nursing skills Self designed questionnaire - 17 items (biographic information, prior knowledge, attitudes & values, positive outcomes, self evaluation) Structured interview (skills & applied knowledge of nurses, based on a case study) Pre & post protocol b) No c) Data
	6	A. D. Brook, T. S. Ahrens, R. Schaiff, D. Prentice, G. Sherman, W. Shannon & M. H. Kollef (1999)	a) To direct nurses in the sedation of patients needing mechanical ventilation b) Protocol	a) Post protocol b) 12 months c) Medical intensive care unit d) USA	a) Patients needing mechanical ventilation (N=321) b) Nurses c) No	a) Positive b) Expanded nursing roles c) Expanded nursing role – following protocol, nurses able to perform tasks previously performed by physicians	Impact of nurse involvement in the protocol suggests that nurses can safety administer approaches previously only administrated by clinicians (p2612). Results detailed in the paper	Anecdotal evidence
	7	A. Bruton & K. McPherson (2004)	a) To improve the care of patients requiring mechanical ventilation by introducing multidisciplinary	a) Pre & post protocol b) 6 months c) General intensive care unit, Southampton (14 beds) d) UK	a) Ventilated patients b) Nurses c) No	a) Positive b) Improved team working Increased clinical freedom Increased job satisfaction Increased clinical knowledge c) Changes in attitudes & perceptions of nursing staff Increased staffawareness	New collaborative approach. Increased respect. Shifts in attitudes from 23% pre to 91% post intervention – nurses believing there was structure in unit	a) Questionnaires Pre & post protocol b) No c) Data - %

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			teams b) Protocol			of issues surrounding weaning patients Increased involvement and feelings of empowerment Reinforced team working Changes to the routine care of ventilated patients	weaning process 53% pre to 68% post - weaning appropriately scheduled	
	8	K. Collins, M. L. Jones, A. McDonnell, S. Read, R. Jones & A. Cameron (2000)	a) To expand the nursing role – increase innovation & non-traditional roles b) Protocol	a) Post protocol b) 2.5 years c) 40 acute NHS trusts d) UK	a) Patients b) Nurses (N=452) c) Yes	a) Positive b) Expanded nursing roles; Increased clinical freedom; Increased job satisfaction; Reduced stress c) Enhanced job satisfaction when working to protocols due to: Increased autonomy; Managing own caseload; Increased responsibility; Improved role clarity * Useful for background on expanded nursing roles & factors associated with job satisfaction	93% (n=471) of those working to protocols felt role enforced job satisfaction compared with 85% (n=78) who did not work to protocols (p6-7) Working to a protocol increased job satisfaction – linked with role clarity (p10) Increased freedom & autonomy valued too	a) Self developed questionnaire - 38 items (job satisfaction, roles, career prospects) Post protocol (after 6 months) b) No c) Data
	9	D. Craig, M. Seller, J. Donoghue & S. Mitten-Lewis (2004)	a) To improve assessment and management of patients with diabetes b) Protocol	a) Pre & post protocol b) Not stated c) Hospital d) Australia	a) Diabetes patients b) Nurses c) No	a) Positive b) Improved team working c) 80% of nurses changed their practice Increased collaboration between staff	Action research approach effective in supporting change. 80% changed their practice in accordance with the evidence.	a) Observational audits of nurses' behaviour Pre & post protocol b) No c) Very basic data - %
	10	M. de Rond, R. de Wit, F. van Dam, B. van Campen, Y. den Hartog, R.	a) To increase nurses use of pain assessment and manageme	a) Post protocol b) Not stated c) 3 hospital settings - medical & surgical wards d) Netherlands	a) Patients of medical and surgical wards (N=315) b) Nurses (N=227) c) Yes	a) Positive b) Increased job satisfaction Improved patient care & understanding c) Positive attitudes towards pain assessment protocol	Nurses varied in their compliance in using the pain assessment process but overall it was quite high.	a) Questionnaire (derived from Wit et al, 1991, 1992) – 16 items, 5 point scale (nurses' attitudes & opinions) Post protocol (6 months)

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		Klievink, R. Nieweg, J. Noort, N. Wagenaar & B. van Campen (1999)	nt in patient care b) Protocol			Better insight into patients' pain Better pain management More attention paid to patients' pain	Nurses were positive about the protocols and reported better insight into patient pain leading to improved patient outcomes	b) No c) Very little data - %
11		M. Dinardo, M. Korytkowski, A. T. Calabrese, G. Zewe, M. Devita, H. Rao & L. M. Siminerio (2002)	a) To develop a nurse initiated treatment protocol for hypoglycaemia b) Protocol	a) Pre & post protocol b) Not stated c) Hospital d) USA	a) Diabetes patients b) Staff nurses (N=101) c) Yes	a) Positive b) Increased job satisfaction; Increased clinical knowledge; Increased clinical skills Improved nurse confidence; Improved knowledge in recognising symptoms; Improved ability to identify high risk patients	Confidence & knowledge – improved percentages Pre and post testing of protocol introduction	a) Self ratings (questionnaire?) Pre & post protocol b) No c) Data & stats
12		D. Dodd-McCue, A. Tartaglia, K. Myer, S. Kuthy & K. Faulkner (2004)	a) To facilitate communication during potential organ donation cases b) Protocol	a) Pre & post protocol, retrospective b) Not stated c) 36 bed medical/ surgery unit d) USA	a) Carers of organ donors/ recipients & their families b) Nurses (N=19) c) Yes	a) Positive b) Improved team working Increased clinical freedom Increased job satisfaction Reduced stress c) Reduction in nurses' perception of role ambiguity, role conflict & role overload – result of providing clear goals, stated guidelines & specific performance expectations Therefore, reduction in role stress	Survey using validated scales (n=19) Interviews (n=16) Retention & turnover rates Role stress – ambiguity, conflict overload – lower. Job dimensions – autonomy, variety, feedback, satisfaction, commitment (p63-66)	a) Questionnaire - 60 items, 7 point scale Global measure of job satisfaction In-depth interviews (general protocol strengths & weaknesses, impact on job responsibilities) - 16 nurses Pre & post protocol b) Job Diagnostic Survey (Hackman & Oldham, 1975) (task id, task significance, autonomy, feedback, variety), internal validity 0.59-0.71

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						Positive change as result of protocol

Improved coordination & communication between staff & between staff & care givers

Improved & consistent training of staff from a multi-disciplinary approach – better team working; More appreciation of the roles of others; High job satisfaction, commitment, autonomy, task significance for nurses with protocol | Presence of protocol, not experience with, is more important for satisfaction (p65) Positive change | Role Questionnaire (Rizzo, House & Lirtzman, 1970) (role stress, ambiguity, conflict, overload, attitudes), reliability 0.78-0.82

Organisational Commitment Questionnaire (Mowday, Steers & Porter, 1979), reliability 0.82-0.93
c) c) Data |

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	13	D. Dodd-McCue, A. Tartaglia, K. W. Veazey & P. S. Streetman (2005)	a) To improve consistency of communication & interaction by clarifying when to approach families regarding potential organ donation b) Protocol	a) Pre & post protocol, retrospective b) 2 years c) Critical care, Virginia d) USA	a) End of life patients after trauma b) Nurses (N=82 at 1st data collection point, N=33 at 2nd, N=33 at 3rd, N=43 at 4th) c) Yes	a) Positive b) Increased job satisfaction Reduced stress c) Reduced role ambiguity for nurses - greater clarity & uniformity of role expectations Reduced role conflict for nurses following protocol implementation Reduced role overload for nurses Positive work attitudes Increased professional, unit & organizational commitment Increased job satisfaction	Training given to all staff. New Chaplin appointed. Reduction in role conflict as protocol set out roles and responsibilities. Implementation of best practice. Increased job satisfaction. Reduced medical errors.	a) Questionnaire - 28 items, 7 point scale (very inaccurate – very accurate); Global measure of job satisfaction; Interviews – semi structured, open ended questions (21 nurses); Pre & post protocol b) Job Diagnostic Survey (Hackman & Oldham, 1975) (task id, task significance, autonomy, feedback, variety), internal validity 0.59-0.71 Role Questionnaire (Rizzo, House & Lirtzman, 1970) (role stress, ambiguity, conflict, overload, attitudes), reliability 0.78-0.82; Organisational Commitment Questionnaire (Mowday, Steers & Porter, 1979), reliability 0.82-0.93 Data & stats
	14	G. B. Edwards & L. M. Schuring (1993)	a) To ensure patients get as much restful sleep as they need when in hospital b) Protocol	a) Pre & post protocol b) 1 week c) Medical intensive care unit d) USA	a) Critically ill patients (N=40) b) Nurses c) Yes	a) Positive b) Expanded nursing roles; Increased job satisfaction; Improved patient care & understanding Nurses feel new sense of responsibility for directing patient care; Satisfaction from implementing a new protocol which benefited patients far outweighed initial frustration when changing practice; Increased sensitivity to patients' needs for uninterrupted sleep	Not clear if information is the result of robust research	Anecdotal evidence

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	15	N. E. Erin, K. Scrivener & T. Simons (2004)	a) To improve quality of life & outcomes for patients with heart failure by integrating evidence into nursing practice b) Protocol, Practice guidelines	a) Pre & post protocol b) Not stated c) Community - home care d) USA	a) Patients with heart failure b) Nurses c) Yes	a) Positive b) Increased clinical knowledge c) Increased nurse knowledge about heart failure disease process, physical assessment, medication, activity & dietary needs	Pre & post test of knowledge following training programme (p609) Audit - increase in teaching about physical activity pre/post protocol.	a) Chart reviews Knowledge assessment form for nurses (questionnaire) Pre & post protocol b) No c) Very little data - %
	16	A. V. Flynn & M. Sinclair (2005)	a) To guide nurses' practice of endotracheal tube suctioning in ICU - evidence based b) Protocol	a) Post protocol b) Not stated c) Intensive care unit d) Republic of Ireland	a) ICU patients b) Nurses (N=19) c) Yes	a) Negative b) Negative impacts c) Protocols restrict nurses' decision making Loss of opportunity for new nurses to develop experience as a consequence of protocols Staff must use their knowledge, intuition & professional judgement to decide when to adapt or deviate from protocol	Protocols, policies & guidelines could be & were adapted with experience & professional judgement (mostly senior staff) More lack of changes or lack of empowerment on the part of the nursing staff	a) Qualitative interviews with nursing staff Analysed using processes influenced by frameworks of Colaizzi (1978), Giorgi (1985) & Streubert & Carpenter (1995) 10 key themes identified Post protocol b) No c) Qualitative data
	17	C. Gale & S. Curry (1999)	a) To provide clinical practice guidelines to enable nurse-led extubation of patients b) Protocol	a) Post protocol b) Not stated c) Cardiac intensive therapy unit, Wales d) UK	a) Patients in therapy following cardiac surgery (N=1017) b) Nurses c) Yes	a) Positive b) Improved team working Expanded nursing roles Increased clinical freedom Increased clinical knowledge Enhanced awareness of professional accountability; Expanded nursing role; Increased autonomy; Empowerment – dissemination of	Expansion in nursing practice (p167) Degree of nurse autonomy (p169) Greater collaboration with colleagues (p169)	a) Audit (number patients weaned & extubated by nurses, early extubation rates, re-intubation rates) Post protocol b) No c) Little data - %

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						scientific & empirical knowledge; Increased collaboration		
	18	B. Gibbon, C. Watkins, D. Barer, K. Waters, S. Davies, L. Lightbody & M. Leathley (2002)	a) To improve staff attitudes towards team working by implementing multidisciplinary team care of stroke patients b) Integrated care pathway	a) Pre & post protocol b) Not stated c) 4 stroke rehabilitation hospital units d) UK	a) Stroke rehabilitation patients b) Nurses c) Yes	a) Positive b) Improved team working c) Increased team vision – improved team working (3 out of 4 units); Increased participative safety – improved team working (3 out of 4 units) Task orientation increased minimally in 2 out of 4 units, no change in 1 unit, marked deterioration in 1 unit. Support for innovation increased minimally in 2 out of 4 units, no change in 1 unit, marked deterioration in 1 unit. External factors (p111)	Team climate inventory – questionnaire administered pre & post introduction of ICP & team notes (p109) Team vision increased in 3 out of 4 units, therefore 3 teams shared goals. Participative safety increased in 3 out of 4 units.	a) Questionnaire - 44 items, 5 point scale Pre & post protocol b) Team Climate Inventory (Anderson & West, 1994) (team vision, participative safety, task orientation & support for innovation), scale reliabilities 0.84-0.94, discrimination validities 0.97-0.98 c) Data
	19	G. Hanlon, T. Strangleman, J. Goode, D. Luff, A. O'Cathain & D. Greatbatch (2005)	a) To assist telephone nurses in offering consistent care advice to callers b) Protocol	a) Post protocol b) Not stated c) 2 NHS Direct call centre sites d) UK	a) NHS Direct callers b) Nurses (N=22) c) Yes	a) Negative b) Negative impacts c) Problems of combining nursing & technology p156: Deskilling, devaluing nursing role; Constrains use of own experience; Limits use of own expertise * Useful background on NHS Direct	Knowledge, Technology & Nursing. Some info on autonomy.	a) In-depth interviews 60-90 minutes Analysed with Nud*ist Post protocol b) No c) Qualitative data
	20	M. Hijazi & M. Al-Ansari (2005)	a) To empower nurses to initiate electrolyte	a) Pre & post protocol b) 2 months c) Medical/ surgical Intensive care unit d) Saudi Arabia	a) Critically ill adults (N=43 pre protocol, N=44 post protocol)	a) Positive b) Increased clinical freedom; Increased job satisfaction c) Increased nurse satisfaction due to		Anecdotal evidence

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			replacement b) Protocol		b) Nurses c) Yes	empowerment		
21		J. Hockley, B. Dewar & J. Watson (2005)	a) To promote quality end-of-life care b) Integrated care pathway	a) Pre & post protocol b) 12 months c) 8 independent nursing homes, Scotland d) UK	a) Nursing home residents b) Nurses c) Yes	a) Positive Improved team working; Expanded nursing roles; Increased clinical freedom; Increased job satisfaction; Improved patient care & understanding; Increased clinical knowledge; Greater openness around dying; Greater understanding & better communication with patients; Greater respect for residents – recognise the importance of this; Increased responsibility - nurses initiating end of life care, joint decisions; Increased consensus around diagnosis; Nurses more proactive; Increased confidence; Increased control over whole situation; Increased involvement in care process; More awareness of dying process; Improved team working – better collaboration, communication, confidence, joint goals; Greater respect for roles of others; Increased confidence & morale – feel valued; Increased knowledge; Empowerment – more awareness, more knowledge	Dying becoming more central to work (p139); Greater openness about dying & death (p140) Important role for nurses – joint decision making & more responsibility (p141); Documentation welcomed - more pro-active & confident staff (p142) Inspired teamwork – carers, nurses & GPs (p143); Nurses more confident with GPs (p144); Increased knowledge (p145); Nurses empowered (p146); Improved morale (p148);	a) Questionnaires Interviews Group discussion ualitative data analysed using NVivo qualitative computer software Pre & post protocol b) No c) Qualitative data

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	22	C. Jones & M. Bonner (2002)	a) To identify domestic violence in antenatal clinic b) Protocol	a) Post protocol b) Not stated c) Antenatal clinic, New South Wales d) Australia	a) Pregnant women attending antenatal clinic (N=159) b) Midwives (N=26) c) No	a) Positive b) Increased job satisfaction Increased clinical knowledge Increased clinical skills Awareness of need to change delivery of care; Midwives felt better able to ask/talk about sensitive issue due to screening questions in protocol - enhanced skills & resources Midwives anxious about asking protocol questions (sensitive issue), reactions of women to questions & expectations of women in terms of action & support; Worried about implementing protocol	Domestic violence screening continued	Anecdotal evidence
	23	M. Kajs-Wyllie, V. Holman & R. Trager Jr (1993)	a) To increase nurse involvement in neuro-rehab rounds for neurologically injured patients b) Protocol	a) Pre & post protocol b) Not stated c) Intensive care unit d) USA	a) Neurologically injured patients b) Critical care nurses c) No	a) Positive b) Expanded nursing roles Improved patient care & understanding Increased clinical knowledge c) Increased knowledge & awareness of rehabilitation Improved motivation to care for patients – they will get better Redirection & expanded nursing focus	No empirical data, but description of increasing nurses awareness of rehabilitation principles for patients. Expanded the focus for critical care nurses from episodic to one more outcome related. The protocol decreased length of stay and increased mobilisation of patients.	a) Nurse questionnaire (pre) Chart reviews (pre) Pre & post (anecdotal) protocol b) No c) No

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	24	J. Kayley, A. R. Berendt, M. J. M. Snelling, H. Moore, H. C. Hamilton, T. E. A. Peto, D. W. M. Crook & C. P. Conlon (1996)	a) To enable safe IV antibiotic therapy at home b) Programme	a) Post protocol b) 2 years c) Community, Oxfordshire d) UK	a) Patients (N=67) b) Community nurses c) No	a) Positive Expanded nursing roles; Increased clinical skills; Extended nursing roles; Increased skills & responsibilities – antibiotic administration, recognition & treatment of anaphylaxis; Increased involvement in discharge planning; Increased involvement in care post discharge	Anecdotal – community nurses 'happy to extend their role'	Anecdotal evidence
	25	N. King, K. Thomas & D. Bell (2003)	a) To improve palliative care in the community by providing an out-of-hours service b) Protocol, Care guidelines	a) Post protocol b) Not stated c) Primary care d) UK	a) Patients dying at home and their carers b) District nurses (N=20) c) No	a) Positive b) Improved team working Increased clinical knowledge c) Improved communication with GPs Problems communicating with Macmillan nurses; Increased knowledge – more information to give to patients; Increased awareness – planning ahead re out-of-hours care	Improved communication (p279) Problems communicating with specialist nurses (p280) Innovation – Bearder bags – better access to drugs (p280) Better forward thinking (p281)	a) Focus groups Analysed with template approach (King, 1998; Crabtree & Miller, 1999) Post protocol (1 year after implementation) b) No c) Qualitative data
	26	J. Kinley & S. Brennan (2004)	a) To standardise the care of oral health b) Protocol, Standard	a) Pre & post protocol, retrospective b) Not stated c) Palliative care unit d) UK	a) Palliative patients (N=50 pre protocol, N=47 post protocol) b) Nurses (N=23) c) Yes	a) Positive b) Increased clinical freedom Increased job satisfaction Increased clinical knowledge Increased clinical skills c) Increased staff awareness of good mouth care practice Increased awareness of where to document the care administered Improvement in staff knowledge & ability	Improvement in knowledge of procedures	a) Audits (designed by Lee et al, 2001) (retrospective) Staff Questionnaire (designed by Lee et al, 2001) (practice, knowledge, documentation) Pre & post protocol (3 months after implementation) b) No c) Little data

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						Empowerment & confidence for staff		
	27	R. Knowles (1996)	a) To improve consistency of pain assessment and management by nursing staff b) Protocol	a) Pre & post protocol b) 6 months c) Post anaesthesia care unit, California d) USA	a) Surgical patients (N=50) b) Nurses (N=29) c) No	a) Positive Improved patient care & understanding; Increased clinical knowledge; Increased clinical skills; Increase in knowledge & understanding; Increased awareness of patients' pain; Improved documentation of treatment given/process followed	Pre & post implementation tests. Improved knowledge Seems to be a fairly intensive lead in to the project with training and raising awareness.	a) Self developed questionnaire, developed from pain literature - 13 items, Likert type & open ended questions (nurses' attitudes, beliefs & knowledge of pain management) Chart audits - correct documentation of pain Pre & post protocol b) No c) Data - %
28 o		R. Kravitz (1993)	a) To standardise the care of skin ulcers to enhance healing b) Protocol	a) Post protocol b) 1 year c) Hospital d) USA	a) All patients b) Nurses c) Yes	a) Positive b) Improved team working; Increased clinical freedom; Increased job satisfaction; Improved patient care & understanding; Increased clinical skills Improved assessment & decision making skills; More interest in caring properly for patients; Rationale for non-compliance – still allowed to use judgement; Increased nurse confidence; Increased interactions with physicians (better team working?); Enhanced sense of pride & accomplishment	Increased confidence (p8); Increased interaction with physicians (p8); Impact on physician practices (p8); Sense of pride & accomplishment (p8)	a) Unit monitoring by members of nursing team Post protocol b) No c) No
29		T. S. Kwan-Gett, P. Lozano, K. Mullin & E. K.	a) To improve the care of asthma patients	a) Pre & post protocol b) 2 years c) Children's hospital d) USA	a) Children with asthma (N=292 pre protocol, N=297 post	a) Positive b) Expanded nursing roles c) Expanded nursing roles – nurses responsible for	Variations usually due to patient related factors (p7) No change to care	Anecdotal evidence

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		Edgar (1997)	b) Clinical pathway, Guidelines		protocol) b) Nurses c) No	monitoring patients' care plans & documenting when & why deviations occurred	provided – control, complex paper method, nurse feedback to doctors (p8) Lessons – training, resources, not rigid (p9)	
	30	L. Lacko, Y. Bryan, C. Dellasega & F. Salerno (1999)	a) To standardise the process used by nurses to detect delirium in elderly patients b) Protocol, Algorithm	a) Post protocol b) 2 months c) 2 units in a large community hospital d) USA	a) Patients – particularly the elderly (N=43) b) Staff nurses (N=25) c) Yes	a) Positive b) Improved patient care & understanding; Increased clinical knowledge; Increased clinical skills c) 90% nurses felt more aware of mental status changes; Improved patient care due to improved knowledge (e.g. difference between delirium & dementia); Improved ability to detect delirium – improved skills & ability Increased sensitivity to other aspects of cognitive impairment	90% said their participation in using the protocol had been helpful because of increased knowledge about delirium and improved patient care (p246) Nurses also felt that standardised system for both assessing and documenting delirium improved care Results indicated that protocol placed additional demands on their time but 90% felt they were prepared for the role.	a) Chart reviews to check if nurses were correctly identifying delirium patients Post protocol b) No c) No
	31	D. T. F. Lee, I. F. K. Lee, A. E. Mackenzie & R. N. L. Ho (2002)	a) To support nursing home staff in taking care of patients with Chronic Obstructive Pulmonary Disease	a) Post protocol, matched RCT b) Not stated c) 45 nursing homes d) Hong Kong	a) Elderly patients with COPD b) Community nurses c) No	a) Positive b) Increased job satisfaction; Improved patient care & understanding; Increased clinical knowledge c) High levels of satisfaction, particularly with frequency of community nursing visits Better understanding of patient condition Improved knowledge;	Satisfaction questionnaire for care home staff – 48 staff (p872) Scores – high level of satisfaction (p873) Limitations (p875)	a) Self developed satisfaction questionnaire, 11 items, 5 point scale (score range 11-55, low to high satisfaction) Post protocol (1 month) b) No c) Little data

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			b) (COPD) Protocol			Increased confidence in patient care		
	32	M. L. Maas, D. Reed, M. Park, J. P. Specht, D. Schutte, L. S. Kelley, E. A. Swanson, T. Tripp-Reimer & K. C. Buckwalter (2004)	a) To improve family involvement in the care of individuals with dementia b) Protocol	a) Pre & post protocol b) 2 years c) 14 nursing homes with dementia special care units d) USA	a) Family carers (N=185) b) Nurses in care homes (N=195) c) Yes	a) Positive b) Increased job satisfaction; Improved patient care & understanding c) More positive perceptions of relationships with family members Acknowledge importance of family input & involvement	78 items - staff perceptions of care giving role 43 items - care giving stress inventory 16 items - attitudes towards family checklist Reliability and validity established	a) Self designed questionnaires, 7 point scale Staff Perceptions of Caregiving Role, 78 items (task burden, role inadequacy, dominion, exclusion); Caregiver Stress Inventory, 43 items (stress related to resident aggression, inappropriate behaviour, safety, resources available to enhance care); Attitudes Towards Families Checklist, 16 items (staff perceptions of whether family caregivers are disruptive, irrelevant to care, should be partners in care); Pre & post protocol Reliability & validity tested in earlier work (Maas & Buckwalter, 1990) Data & stats
	33	C. MacArthur, H. R. Winter, D. E. Bick, R. J. Lilford, R. J. Lancashire, H. Knowles, D. A. Braunholtz,	a) To develop & implement a new midwifery led model of postnatal care b) Protocol,	a) Post protocol, cluster RCT b) 18 months c) 36 randomly selected GP clusters, West Midlands Health Region d) UK	a) Women – postnatal care (N=1087 in intervention group, N=977 in control group) b) Midwives (N=42 in intervention group, N=38 in	a) Positive b) Increased job satisfaction c) Increased satisfaction with organisation of postnatal care and increased satisfaction with own roles for intervention midwives	Intervention midwives more satisfied with organisation of postnatal care than control midwives (p38-9) Intervention midwives much more satisfied with own roles (p38-9)	a) Self designed satisfaction questionnaire (organisation of postnatal care, role of midwife) Post protocol only b) No c) Data & stats

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		C. Henderson, C. Belfield & H. Gee (2003)	Guidelines		control group) c) No		Intervention allows care more appropriate to individual needs (p38-9)	
	34	C. Macduff, B. J. M. West & S. Lawton (2000)	a) To enable nurse-led treatments for minor injuries b) Protocol, Algorithms	a) Post protocol b) Not stated c) Community hospitals – Grampian Healthcare Trust d) UK	a) Patients with minor injuries (N=79) b) Nurses (N=80) c) Yes	a) Positive b) Improved team working; Expanded nursing roles; Increased job satisfaction; Increased clinical knowledge; Increased clinical skills Nurses significantly more involved in provision of care; Improved clinical knowledge (78% nurses); Improved patient assessment skills (78%); Improved clinical treatment skills (73%, significant association with role development); Improved awareness of professional accountability (73%, significant); Improved confidence in professional role (53%); Improved job satisfaction (55%); Improved working relationships with doctors (40%) and patients (42%) (both significant association with role development)	Training needs & legal issues – skills based programme for university (p277) Questionnaire – positive & negative aspects of the development Patient care (p278) Nurses not involved with protocols - lost confidence in role & working relationship with colleagues, disempowerment (p279) Increased skills & confidence, Comments about protocols & course positive (p280)	a) Self designed, semi-structured questionnaires for nurses (positive & negative aspects of role development, perceptions of impact on knowledge & skills) Post protocol b) No c) Data - %
	35	E. Manias & A. Street (2000)	a) To guide clinical activities & promote quality patient	a) Post protocol b) Not stated c) 16 bed critical care unit d) Australia	a) Critical care patients b) Registered nurses (N=6) c) Yes	a) Positive & negative Improved team working; Increased clinical freedom; Increased job satisfaction; Negative impacts; Increased nurse	Nurses adhered closely to protocols (p1470) Protocols mediated communication with doctors –	a) In-depth interviews (2 with each nurse – how protocols affect decision making activities) Focus groups Analysed using textual

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			b) Protocol, Policy			confidence in discussing treatment decisions; Protocols mediated communication with doctors & other nurses – legitimised decisions; Increased power/ability to assert power through protocol use; But, constrained nurses' knowledge by limiting the kinds of knowledge used	nurses more confident (p1470) Conceal own knowledge & practices of resistance (p1471) Nursing gaze & surveillance practices – control (p1472) Simultaneously enabled & constrained practice (p1474)	analysis (Holloway & Wheeler, 1996) Post protocol only b) No c) Qualitative data
	36	A. F. Marbrook & B. Dale (1998)	a) To enable a nurse led 'walk-in' service allowing nurses to discharge patients without referral to others b) Protocol	a) Post protocol b) 12 months c) Minor injuries walk-in unit, community hospital, West Sussex d) UK	a) People with minor injuries (N=9897) b) Emergency nurse practitioners (N=4) c) No	a) Positive b) Expanded nursing roles c) Expanded nursing role – treat & discharge patient without doctor Increased responsibilities – requesting & interpreting radiographs, administering medication	Allowing the emergency nurse practitioners to request radiographs and administer certain medication determined the apparent effectiveness of the service based on the outcome data (p267)	a) Audits Post protocol b) No c) Basic data
	37	J. Marshall, C. Edwards & M. Lambert (1997)	a) To support nurses in the administration of medicines, ensuring safe transition from doctors to nurse-led care	a) Post protocol b) 6 months c) Accident & Emergency, Norwich d) UK	a) A & E patients (N=2925) b) Nurses (N=6) c) No	a) Positive b) Expanded nursing roles; Increased job satisfaction; Increased clinical knowledge; Increased clinical skills c) Protocol implementation beneficial to whole department – improved service quality; Nurse practitioners able to deliver holistic care to patient; NPs now	Limited Whole A&E found protocol beneficial (p236) Increased job satisfaction of the nurses involved in using it.	a) Audits Post protocol (6 months) b) No c) No

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			b) Protocol			independent practitioners – expanded role, skills, ability; Increased job satisfaction * Useful background info on legal/ professional issues		
	38	A. M. Mayo, B. L. Chang & A. Omery (2002)	a) To act as guidelines to aid nursing care practice for telephone nurses b) Protocol, Guidelines	a) Post protocol b) Not stated c) 7 settings in the field of telephone nursing, California d) USA	a) Patients who called the service (excluding paediatric, obstetric & psychiatric calls) (N=157) b) Telephone nurses (N=32) c) Yes	a) Negative b) Negative impact c) Inverse relationship between availability of protocols & quality of nursing – as more protocols were available, the quality of nursing declined. But, extent of use of protocols had no significant effect on the quality of the nursing process. Re inverse relationship, authors state that 'it is not clear exactly why this association exists' p215; Further investigation needed.	Protocols available for 79% of calls Degree to which nurses used any protocol varied, from not much (24% - 1%) to all (100%) More than half of the protocols were used less than 100% Also, no significant relationship found for use of protocols and degree of involvement in development & implementation. o relationship between availability & use of protocols and patient outcomes	a) Telephone nurses' self designed questionnaire (nurse demographics, protocol use and availability) Advice nurse structured implicit review form, developed by using method described by Pearson, Chang, Lee, Kahn & Rubenstein (1997) (measure of quality of nursing process i.e. assessment, planning, implementation, patient interaction – 5 nurse experts listened to taped calls between nurses & patients & completed form for each) Call tracking form (measure of when & to what extent protocol used with each call) Post protocol b) Content validity reviewed by nursing staff Inter-rater reliability of 5 nurse experts = 0.75-0.80 Little data - %

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	39	R. J. Mendoza, D. J. Pittenger, F. S. Savage & C. S. Weinstein (2003)	a) To enable multidisciplinary assessment and intervention management of risk in wheelchair driving b) Protocol	a) Post protocol b) Not stated c) Health care facility d) USA	a) Wheelchair users b) Nurses c) No	a) Positive b) Improved team working c) Improved inter-departmental communication & cooperation	No data	Anecdotal evidence
	40	L. Miller (1995)	a) To maintain skin integrity & ensure consistency of nursing care b) Protocol, Standard of care	a) Post protocol b) Not stated c) Hospital rehabilitation unit d) USA	a) Patients b) Nurses c) No	a) Positive b) Increased clinical knowledge Increased clinical skills c) Nurses are better able to assess a wound & determine the need for treatment Improvement in nurses' assessment & evaluation knowledge & skills	Descriptive data on improvement of assessment skills of nurses and for evaluating their knowledge and skills. Chart reviews indicate consistency among the nursing staff using the care plan and in selection of intervention. Wound photographs show nursing staff are properly evaluating the stages of pressure ulcers. Cost of air mattresses reduced.	a) Chart reviews of steps followed Wound photographs studied Post protocol b) No c) No
	41	C. T. Milne & L. C. Pelletier (1994)	a) To improve patient care through the use of specific	a) Post protocol b) Not stated c) 36-bed medical/ surgical unit in a community hospital	a) Patients b) Nurses c) No	a) Positive b) Improved team working; Expanded nursing roles; Increased clinical knowledge Improved communication	Nurse assimilate physical assessment & psychosocial skills (p162) Feedback from staff	Anecdotal evidence

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			daily care plans b) Clinical pathway, Critical pathway	d) USA		& collaboration between nurses & doctors; Increased knowledge – learning from experience; Nurses assimilate physical assessment & psychosocial skills on a routine basis; Ability to recognise clinical problems at an earlier stage	positive (p162) Inexperienced nurses positive about organised format providing assistance in care (p162)	
	42	C. A. Monturo, P. D. Rogers, M. Coleman, J. P. Robinson & M. Pickett (2001)	a) To help patients recovering from radical prostate surgery and their partners to overcome difficulties discussing sexual function b) Protocol	a) Post protocol b) 2 months c) Community - patients' homes d) USA	a) Post radical prostate cancer surgery patients & partners b) Nurses c) Yes	a) Positive b) Increased job satisfaction Improved patient care & understanding Increased clinical knowledge Increased clinical skills c) Increased confidence & skills Increased knowledge & self awareness Understanding of the importance of verbal & non-verbal cues; Understanding of the importance of developing a trusting relationship with the patient	1. Knowledge & self awareness build skill & comfort 2. Use of structured approach to deal with challenging situations 3. Need for a trusting relationship as a basis for difficult discussions 4. Verbal & non verbal cues – importance of…	Anecdotal evidence
	43	E. Murray & D. Fitzmaurice (1996)	a) To provide guidelines for nurses about how to manage daily Warfarin levels in primary care b) Protocol	a) Post protocol b) 12 months c) Primary - Inner city clinic d) UK	a) Out-patients taking Warfarin tablets (N=49) b) Nurses in clinics c) Yes	a) Positive b) Expanded nursing roles Increased clinical skills c) Extensions to roles Complete model of care New skill development	Nursing perspective: 'Managing clinic offered the practice nurse a new and rewarding extension to her role' (p31) 'Satisfying to offer complete model of care' (p31) 'Practice nurses develop new skills'	Anecdotal evidence

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							(p32) One clinic closed due to lack of involvement of nurses & no autonomous management of clinic	
	44	A. O'Cathain, F. C. Sampson, J. F. Munro, K. J. Thomas & J. P. Nicholl (2004)	a) To enable NHS direct nurses to provide advice on a 24-hour advice line by using computerised decision support software b) Algorithm, Guidelines	a) Post protocol b) Not stated c) 12 NHS direct sites d) UK	a) Callers b) Nurses (N=24) c) Yes	a) Positive & negative b) Improved patient care & understanding Negative impacts c) Nurses felt software helped provide consistency of advice But, limited ability to use own experience & knowledge	Qualitative data analysed using framework analysis	a) Semi-structured interviews Analysed using framework analysis (Richie & Spencer, 1994) with Winmax software (Kuckartz, 1998) Post protocol only b) No c) Qualitative data
	45	F. W. O'Connor, E. C. Devine, T. D. Cook, V. A. Wenk & T. R. Curtin (1990)	a) To facilitate an increase in nurses psycho-educational care with no increase in staffing b) Protocol	a) Pre & post protocol b) Not stated c) 2 general surgery hospital units d) USA	a) Surgery patients (N=75 pre protocol, N=76 post protocol) b) Nurses (N=31) c) Yes	a) Positive b) Improved patient care & understanding c) Nurses increased information given to patients – better communication Increased psycho-social support given to patients	Concern that in follow up protocol they would neglect other aspects of work - not found Details of outcomes (p17)	a) Questionnaires Full day observations of nurses Pre & post protocol b) No c) Little nurse data
	46	D. Parker, T. Claridge & G. Cook (2005)	a) To specify & evaluate best clinical practice & improve	a) Post protocol b) 12 months c) District General Hospital d) UK	a) Patients b) Nurses (N=182) c) Yes	a) Negative b) Negative impacts Practice controlled by ICPs; ICPs take away ability to use professional autonomy when dealing	10 attitude dimensions Nurses more positive attitudes (p16); Senior & junior staff – juniors	a) Self designed questionnaire - 76 items, 5 point scale, developed from 21 interviews & 11 focus groups (attitudes towards ICPs)

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			a) patient care b) Integrated care pathway			with patients	more negative (p17); Main problems – not a flexible tool, control their practice & autonomy, lack of individualised care (p19); Top down - imposed (p20)	Factor analysis revealed 10 dimensions, accounting for 57% of variance in responses Post protocol b) α = 0.52-0.93 for each factor c) Data & stats
	47	T. Porrett, C. H. Knowles & P. J. Lunniss (2003)	a) To allow nurses to manage the treatment of anal fissure b) Protocol	a) Pre & post protocol b) 3 years c) District general hospital d) UK	a) Patients with idiopathic anal fissure (N=135) b) Nurses c) No	a) Positive b) Expanded nursing roles; Increased clinical skills c) Expanded nursing role & skills – nurse led protocol effective	Nurse-led rates of healing were at least equivalent to that of the consultant (nurse practitioner 52% to 46% consultant) Nurses had slightly lower rate of non compliance (8% versus 14% for consultant) The nurse practitioner did not make any misdiagnoses. Paper suggests that there is evidence to support the nurse-led protocol (p65)	a) Audits (pre) Competence of nurse practitioner reviewed by consultant Pre & post (anecdotal) b) No c) No
	48	B. T. Pun, S. M. Gordon, J. F. Peterson, A. K. Shintani, J. C. Jackson,	a) To improve sedation and delirium monitoring b) Protocol,	a) Post protocol b) 18 months c) Intensive care units (2 sites) d) USA	a) ICU patients (N=711) b) Nurses (N=64) c) Yes	a) Positive b) Improved team working; Increased job satisfaction; Improved patient care & understanding; Increased clinical skills	Implementation survey questionnaire - 55 nurses High degree of comfort and	a) **Implementation survey questionnaire Post protocol (6 months after implementation) (p1204)** b) No

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		J. Foss, S. D. Harding, G. R. Bernard, R. S Dittus & E. W. Ely (2005)	Guidelines			High degree of comfort & satisfaction using protocol; Improved ability of team to reach consensus – better team working & communication; Greater understanding of the patient's condition; Improved organisation of their overall neurological assessment of patients	satisfaction; Improved team consensus and organisation of assessments; Barriers - time (most frequent), doctors 'buy in', confidence	c) Data - %
	49	R. Ryan, J. Davoren, H. Grant & L. Delbridge (2004)	a) To provide guidelines for nurse initiated patient discharge b) Protocol, Clinical guidelines	a) Post protocol b) 3 months c) 23hr care centre, part of hospital d) Australia	a) Patients (N=1601) b) Nurses c) No	a) Positive b) Expanded nursing roles; Increased clinical freedom c) Significant cultural shift for organisation Increased autonomy & authority for nurses Nurses coordinate patient management & monitor outcomes		Anecdotal evidence
	50	L. A. Rymaszewski, S. Sharma, P. E. McGill, A. Murdoch, S. Freeman & T. Loh (2005)	a) To reconfigure roles in the outpatient orthopaedic team to reduce waiting times for patients b) Protocol	a) Post protocol b) 12 months c) Orthopaedic outpatients clinic, part of hospital, Glasgow d) UK	a) Orthopaedic out-patients (N=4568) b) Nurses c) Yes	a) Positive Increased job satisfaction; Increased clinical skills; Nurses trained in specialist roles – increased skills & abilities; Improved morale & personal development due to team approach (saw patients appropriate to skills & expertise)	The team approach lead to improved morale & personal development of health professionals (survey) as they saw patients appropriate to their skills & experience (p178)	a) Survey – no details given 'as assessed by a survey' p178 Post protocol b) No c) No
	51	G. Scott Stephens, M. Pokorny & J. M. Bowman (1997)	a) To assist nurse triage of patients complaining of cardiac symptom	a) Pre & post protocol, retrospective b) Not stated c) Emergency room d) USA	a) Patients with suspected myocardial infarction (N=40 - different patients pre & post)	a) Positive b) Expanded nursing roles; Increased clinical skills c) Increased initiation of triage protocols (significant improvement) Protocols assisted nurses in documenting signs &	Before in-service education - 10% patients had triage protocols initiated by a nurse After in-service education - 75% patients had triage	a) Chart reviews (retrospective) Pre & post protocol b) No c) Basic data - %

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			distress b) Protocol, Standing order		b) ER triage registered nurses (N=25) c) Yes	symptoms the patient was experiencing	protocols initiated by a nurse (p192) Aided nurses in documenting signs & symptoms	
	52	M. Shanahan & S. Walton (1995)	a) To provide a standard of patient care through better management of anaemia b) Protocol	a) Post protocol b) 1 month c) Secondary - Community based hospital d) USA	a) Out-patients requiring dialysis b) Nurses c) Yes	a) Positive Improved team working; Expanded nursing roles;Increased clinical freedom; Increased job satisfaction; c) Improved nursing satisfaction p476; Leadership role for nurses;Better nurse-physician communication - team working; Autonomous decision making – sense of pride	Nursing staff able to establish a standard of care for anaemic management (p473) Communications between nurses and physicians greatly improved (p476); Nurse leadership role, satisfaction, autonomous decision making	Anecdotal evidence
	53	R. Shaw, L. Wallace, M. Cook & A. Phillips (2004)	a) To provide a standard for 'hands-off' assistance with early breastfeeding b) Protocol	a) Post protocol, RCT b) Not stated c) Postnatal wards, 4 hospital sites d) UK	a) New mothers (N=342) b) Midwives (N=99) c) Yes	a) Positive b) Improved patient care & understanding c) Good practice reinforced	Reinforces good practice (p21) Encouraging change in perspective (p22)	a) Questionnaire – 75 midwives (anonymous) Focus groups – 12 midwives in total across 3 groups Semi-structured interviews – 12 midwives Analysed using interpretative phenomenological analysis Triangulation of results Post protocol b) No c) Qualitative data
	54	M. F. Shepard, B. A. Elliott, D. R. Falk & R. R. Regal (1999)	a) To provide a screening tool to assess for domestic	a) Pre & post protocol b) Not stated c) Community - maternal & child health visiting programme	a) Women b) Public health nurses c) No	a) Positive b) Improved team working; Improved patient care & understanding; Increased clinical knowledge c) Nurses greatly increased	Provision of more information to women (p363-4) More likely to raise the topic, more knowledgeable &	Anecdotal evidence

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			violence b) Protocol	d) USA		the extent to which they intervened by providing women with information about resources available Nurses more knowledgeable, comfortable & willing to work collaboratively with community resources; Difficult to broach sensitive subject with some women	more likely to use resources	
	55	R. M. Shepherd, M. London & G. J. M. Alexander (1999)	a) To provide nurses with guidelines concerning treatment of patients with alcohol problems b) Guidelines	a) Pre & post protocol, retrospective b) 12 months c) Medical wards d) UK	a) Patients on medical wards b) Nurses c) Yes	a) Positive b) Increased clinical skills c) Better quantitative patient histories taken	There was an increase in qualitative notes taken by nurses from 4 to 19%. They failed to use CAGE effectively (identified 35 cases when only 2 warranted it) but they were not instructed in its use	a) Audit of notes (792, 690, 497, 290 patients' notes audited on 4 separate occasions Pre & post protocol b) No c) Little data
	56	K. L. Shrake, J. E. Scaggs, K. England, J. Q. Henkle & L. E. Eagelton (1996)	a) To reduce costs through using a respiratory care assessment-treatment program b) Program	a) Post protocol b) 2 years c) Hospital d) USA	a) Cardio-pulmonary patients (N=4420) b) Nurses c) No	a) Positive b) Improved team working; Increased job satisfaction c) Perceived improvement in staff morale & satisfaction with patient care role & interactions with colleagues; Improved communication & team working (nurses now part of team)	Anecdotal observation - perceived improvement in staff moral and satisfaction with patient care (p709) (no data) Expect to follow this up	Anecdotal evidence
	57	S. Smith, G. Bury, M. O'Leary, M. Shannon, A. Tynan, A. Staines & C.	a) To create a shared care model for diabetes – nurses and	a) Post protocol, cluster RCT b) 18 months c) 30 GP practices, North Dublin d) Ireland	a) Patients with type 2 diabetes (N=96 in intervention group, N=87 in control group)	a) Positive b) Increased job satisfaction c) Increased confidence in providing care		a) Semi structured interviews with nurses (opinions of protocol) Post protocol (1 year after implementation b) No

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Table 2.7	Ref ID	Authors Publication Year	a) Protocol aim b) Terms used	a) Study design b) Study duration c) Study setting d) Country	a) Population b) Protocol users c) Primary focus on staff?	a) Protocol impact on staff – positive or negative b) Impact category c) Specific protocol impacts on staff	Study outcomes	a) Outcome measures used b) Validated/ reliable scales? c) Staff impact data reported?
		Thompson (2004)	b) GPs Intervention		b) Practice nurses c) No			c) No
	58	C. M. Spiers (2003)	a) To enable nurse-led thrombolysis b) Protocol, Integrated care pathway	a) Review of studies b) Not stated c) Hospitals d) UK	a) Patients with acute myocardial infarction b) Nurses c) No	a) Positive b) Improved team working; Expanded nursing roles; Increased clinical freedom; Increased clinical knowledge c) Expanded nursing role – nurses responsible for patient triage, delivery of care (thrombolysis) and evaluation of care Additional nursing roles – education, training, audits Improved collaboration between nursing and medical practitioners Greater awareness of best practice Increased autonomy	Role expansion & recognition of unsuspected medical conditions (p36) Changes in role as treatment advances (p37)	
	59	M. P. Stanton & G. S. Nix (2003)	a) To teach hypertension patients about hypertension in order to improve consistency of education and compliance with treatment b) Protocol, Clinical guidelines	a) Pre & post protocol b) 4 months c) Rural community healthcare clinic d) USA	a) Out-patients with hypertension (N=19) b) Nurses (N=3) c) Yes	a) Positive b) Increased job satisfaction Improved patient care & understanding c) Some significant improvements in staff satisfaction following protocol implementation More consistent info provided to patients	Patient & staff satisfaction – 3 months before & 1 month after implementation of protocols Scales (reliability not validity) – attitudes, job characteristics, management style & organizational commitment Said but no data about changes in staff & patient satisfaction – significant	a) Self designed satisfaction questionnaires (developed at local hospital & adapted for study), 5 point scale (attitudes towards work environment, job characteristics, policies/procedures, management style, communication, compensation, benefits, commitment) Pre & post protocol (3 months before, 1 month after) b) Scale reliability 0.78-0.9 c) No

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							Materials to do excellent work – managers feel outcomes number 1 priority Increased documentation More commitment	
	60	L. Stratton (1999)	a) To improve pain management care b) Process & policy development	a) Pre & post protocol b) 3 years c) Community hospital, California d) USA	a) Patients b) Nurses (N=18) c) Yes	a) Positive b) Increased job satisfaction Increased clinical knowledge c) Improved knowledge about pain management More positive attitudes	Scores most likely demonstrate a true change in knowledge and attitudes regarding pain management practices (p8)	a) Questionnaire - 39 items, developed by Ferrell (1996) (nurses' knowledge & attitudes on pain management - NKA Survey) Pre & post protocol b) Internal consistency > 0.7 Test-retest reliability > 0.8 c) Data & stats
	61	D. Sulch, A. Evans, A. Melbourn & L. Kalra (2002)	a) To improve the process of care in stroke rehabilitation b) Integrated care pathway	a) Post protocol b) Not stated c) Hospital, London d) UK	a) Stroke rehabilitation patients (N=152) b) Nurses c) Yes	a) Positive Improved team working; Improved patient care & understanding ; Increased clinical skills; Improved assessment & documentation; Improved communication with GPs & patients	ICPs – better documentation & improved communication with pts & GPs (p177) No difference in multidisciplinary team coordination	a) Audits Post protocol b) No c) Little data - %
	62	D. L. Vance (2003)	a) To help decision making about the use/non use of restraints in an intensive care unit	a) Pre & post protocol b) Not stated c) Critical care unit, 8 beds, Ohio d) USA	a) CCU patients (N=90) b) Nurses (N=11) c) Yes	a) Positive b) Increased clinical knowledge c) More awareness of when to use restraints – 36% reduction in inappropriate restraint use 36% respondents (n=11) agreed that the protocol influenced their practice	Self report – influence on practice. Documentary comparison – appropriateness of decision making Pre & post protocols stats	a) Nurse questionnaire - 6 questions, 5 point scale (ease, usefulness, clarity & practicality of protocol) Post protocol only Data on restraint use – observation, chart reviews Pre & post protocol b) No c) Data - %

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			b) Protocol, Clinical pathway, Algorithmic guidelines					
	63	B. van Meijel, M. van der Gaag, R. S. Kahn, M. H. F. Grypdonck (2003)	a) To provide a relapse prevention plan detailing the early warning signs of psychosis b) Protocol	a) Post protocol b) Not stated c) Psychiatric care – outpatients, day care, hospitalised d) Netherlands	a) Patients with schizophrenia (N=40) b) Nurses (N=26) c) No	a) Positive b) Improved patient care & understanding c) 75% nurses reported acquiring new knowledge about the patient as a result of the protocol	Data from survey but little detail of the measures	a) Questionnaires – little info given Post protocol b) No c) Data - %
	64	A. van Wersch, J. Bonnema, B. Prinsen, J. Pruyn, Th. Wiggers & A. N. van Geel (1997)	a) To improve continuity of information b) Protocol	a) Post protocol b) Not stated c) 2 hospitals and community d) Netherlands	a) Breast cancer patients (N=53) b) Nurses (N=47) c) Yes	a) Positive b) Improved team working Increased job satisfaction; Improved patient care & understanding; Improved communication of information with patients – 94% nurses; Improved knowledge about the roles of other care professionals in breast cancer patient care – 96% staff; Improved team working – 90% staff felt better able to fit their care to the care given by others; Increased support for patients – 71% nurses; More positive attitude to protocol - nurses	Differences between nurses and other groups eg 94% nurses give patients more information (p181-2) Nurses have more positive attitudes - younger and female (p184)	9) Evaluative questionnaire (use & utility of protocol, continuity of info, patient education) Post protocol (6 months after) 10) No 11) Data -%

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Appendix 3a: Method: National survey of nurses, midwives and health visistors

3.1 Survey procedure

A postal and web-based survey of nurses, midwives and health visitors was distributed to random samples of nurses, midwives and health visitors between October 2007 and January 2008.

For the first two groups of professionals, the Royal College of Nursing (RCN) and the Royal College of Midwives (RCM) randomly drew members from their data bases. Surveys were distributed to these samples by a third party distribution agent. Each participant was sent a copy of the survey and a participant information sheet providing details about the aims of the research, instructions for completing the survey and information on how the data will be treated.

For health visitors it was not possible to draw a random sample of members so a different distribution strategy was adopted. Five thousand questionnaires were sent out via the Community Practitioners' and Health Visitors' Association (CPHVA).

In all cases, participants were asked to return the completed questionnaire to the research team at the University of Sheffield using the reply paid envelope. In this way, participants were assured of the confidentiality of their responses. A two week follow-up questionnaire reminder was sent to RCN and RCM members. The distribution method meant that it was not possible to send reminders to CPHVA members.

Participants were also given the option to complete the survey on-line by directing them to the project's website or, in the case of health visitors, to the survey link found on the CPHVA's website.

3.2 Questionnaire Design

The questionnaire was developed through a small-scale piloting study conducted between July and August 2007. Overall, the results from the piloting phase indicated that the questionnaire had high face validity, that the instructions were clear and easy to follow and the items were deemed appropriate for the three professional groups.

The final questionnaire was eight A4 pages in length and consisted of 35 questions divided into 4 sections that collected data on the following:

- **Section 1** explored individual understanding of the meaning and purpose of variants of standardised care. It gathered data on the variant of standardised care that most influenced their practice and the range of contexts and tasks where standardised care is used. Section 1 also gathered data on the degree to which a respondent was involved the development, implementation, use and audit of standardised care.

- **Section 2** assessed individuals' experiences of standardised care in their place of work including the degree to which their organisation was perceived as encouraging their involvement in developing and reviewing standardised care procedures as well as expectations regarding compliance with standardised care.

- **Section 3** focused on individuals' perceptions of a range of job characteristics including the degree of control over their work, workload, their well-being and overall job satisfaction as well as their overall views about their organisation.

- **Section 4** asked for demographic and contextual information.

3.3 Measures

Table 3.1 presents information on the measures that were used in the survey including the total number of items per measure, example items, response scales, scale reliabilities as well as the sources we drew upon to adapt or develop the scales.

3.4 Data analysis

Data were analysed using the Statistical Package for the Social Sciences (SPSS, version 15.0). Prior to the main analyses, the data were screened for outliers and distributional errors which included obtaining values for skewness and kurtosis in order to ascertain the extent to which the data were normally distributed.

Descriptive statistics (e.g. means and standard deviations) were used to identify sample characteristics including proportion of respondents who were male or female, types of contexts and tasks where standardised care is introduced and used. Principal components factor analysis was used to identify the dimensions underlying participants' responses to the survey items. The reliability of the scales used was examined using the alpha coefficient.

Hierarchical regression analysis was used to examine the impact of the properties of standardised care procedures on the aforementioned work outcomes. Separate hierarchical regression analyses were conducted for each of the outcome variables. Within each of these regressions, the effects

of age, gender, organisational tenure and job type were controlled in Step 1 followed by the 'enabling' features of standardised care (flexibility, transparency and involvement) and ideological fit in Step 2.

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Table 3.1. Information on measures used in questionnaire

Variable name	No of items	Example items	Response scale	Reliability	Source	Section/ sub-section
Meaning of different standardised care terms	4	▪ Protocol ▪ Clinical guideline ▪ Care pathway ▪ Algorithm/Flowchart	▪ 'A specific task or procedure' ▪ 'Set of procedures that are part of patient journey' ▪ 'Procedures for overall patient journey' ▪ 'None of these'		Review of the literature	1/1.1
Status of different standardised care terms	4	▪ Protocol ▪ Clinical guideline ▪ Care pathway ▪ Algorithm/Flowchart	▪ Mandatory ▪ Advisory ▪ Information ▪ None of these		Designed for the present study	1/1.2
Purpose of standardised care	6	▪ Helps reduce variation un quality of care ▪ Provides clarity regarding care standards	Likert 1-5 (1 = strongly disagree; 5 = strongly agree)		Modernisation Agency/ NICE (2002)	1 /1.3
Involvement in patient care	1	Amount of time spent providing direct patient care	Likert 1-5 (1=never; 5=all of the time)		Designed for the present study	1/1.5
Contribution to standardised care	6	In last 2 years, to what extent have you: ▪ Led the development of standardised care ▪ Used standardised care	Likert 1-5 (1=not at all; 5=great extent)		Designed for the present study	1/1.6
Procedures used to deliver standardised care	4	▪ Protocols ▪ Clinical guidelines ▪ Care pathway ▪ Algorithm/Flowchart	Likert 1-5 (1=not at all; 5=great extent)		Review of the literature	1/1.7
Type of standardised care used most often	6	▪ Protocols ▪ Clinical guidelines ▪ Care pathway	Forced – choice		Review of the literature	1/1.8
Amount of time spent providing patient care using standardised care	1	▪ How much of your direct patient care involves giving some form of standardised care?	Likert 1-5 (1= none of my direct care; 5 = all of my direct care)		Designed for the present study	1/1.9

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Table 3.1 continued

Variable name	No of items	Example items	Response scale	Reliability	Source	Section/ sub-section
Status of standardised care in workplace	3	▪ Mandatory ▪ Advisory	▪ Likert 1-5 ▪ 1=very little extent ▪ 5=very great extent	-	Designed for the present study	1/1.10
Compliance with standardised care	1	▪ Please indicate how much of the time you comply with standardised care	▪ Likert 1-6 ▪ (1= never; 6 not applicable)	-	Designed for the present study	1/1.11
Types of tasks where standardised care is used	7	▪ Health screening ▪ Prescribing	▪ Likert 1-6 ▪ (1= never; 6 not applicable)	-	Designed for the present study	1/1.12
Involvement in standardised care	5	▪ Staff responsible for delivery of care are involved in developing standardised care ▪ I have the opportunity to suggest improvements to standardised care	▪ Likert 1-5 ▪ (1 = strongly disagree; 5 = strongly agree)	0.88	Designed for present study drawing on Adler and Borys (1996)	2/2.1
Climate for reviewing standardised care	3	▪ The 'standardised forms of care' are regularly reviewed ▪ Deviations from standardised care are regularly analysed	▪ Likert 1-5 ▪ (1 = strongly disagree; 5 = strongly agree)	0.80	Designed for present study drawing on Adler and Borys (1996)	2/2.1
Climate for rule-following	▪ 3	▪ People follow strict 'standardised care' at all times	▪ Likert 1-5 ▪ (1 = strongly disagree; 5 = strongly agree)	0.82	Bacharach, Bambergerg and Conley (1990)	2/2.1
Transparency of standardised care	4	▪ I understand the rationale behind the 'standardised care' procedures I implement	▪ Likert 1-5 ▪ (1 = strongly disagree; 5 = strongly agree)	0.91	Designed for present study drawing on Adler and Borys (1996)	2/2.2
Evidence – base of standardised care	2	▪ The 'standardised care' in my work is evidence-based	Likert 1-5 (1 = strongly disagree; 5 = strongly agree)	0.79	Designed for present study	2/2.2

The Contribution of nurses, midwives, and health visitors to protocol-based care and its variants, and the impact of their contribution on patient and staff outcomes, quality and costs of care

(SDO Project 08/1405/079)

Table 3.1 continued

Variable name	No of items	Example items	Response scale	Reliability	Source	Section/ sub-section
Flexibility in using standardised care	4	▪ I have the freedom to deviate from 'standardised care' if the situation calls for it	Likert 1-5 (1 = strongly disagree; 5 = strongly agree)	0.87	Designed for present study drawing on Adler and Borys (1996)	2/2.2
Rationale for introduction of standardised care	2	▪ The 'standardised care' we have in place is for management to cover their backs	Likert 1-5 (1 = strongly disagree; 5 = strongly agree)	-	Designed for present study	2/2.2
Training in use of standardised care	1	▪ I have had sufficient training in the 'standardised care' that I am expected to follow'	Likert 1-5 (1 = strongly disagree; 5 = strongly agree)	-	Designed for the present study	2/2.2
Individualised patient care	4	▪ How frequently do you... deviate from standardised care procedures in order to deliver better patient care?	Likert 1-5 (1 = Never; 5 = always)	0.75	Designed for present study	2/2.3
Professional autonomy	3	▪ I have significant autonomy in determining how I do my job	Likert 1-5 (1 = strongly disagree; 5 = strongly agree)	0.90	Spreitzer (1995) – Work Empowerment sub-scale	3/3.1
Self-efficacy	3	▪ I am confident about my ability to do the job	Likert 1-5 (1 = strongly disagree; 5 = strongly agree)	0.92	Spreitzer (1995) – Work Empowerment sub-scale	3/3.2
Task routineness	6	▪ Are unit members performing repetitive activities in doing their jobs?	Likert 1-5 (1 = very little extent; 5 = very great extent)	0.71	Withey, Daft & Cooper (1983)	3/3.3
Work demands (timing)	3	▪ Do you have too much to do in too little time?	Likert 1-5 (1 = very little extent; 5 = very great extent)	0.66	Haynes, Wall, Bolden and Rick (1999)	3/3.3
Skill use	3	▪ Do you use a variety of skills?	Likert 1-5 (1 = very little extent; 5 = very great extent)	0.55	Adopted from Parker (1998)	3/3.3

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Table 3.1 continued

Variable name	No of items	Example items	Response scale	Reliability	Source	Section/ sub-section
Role clarity	3	▪ Do you know what is expected of you at work?	Likert 1-5 (1 = very little extent; 5 = very great extent)	0.64	Haynes *et al* (1999) Rizzo, House and Lirtzman (1970)	3/3.3
Role conflict	3	▪ Do your colleagues make conflicting demands on you?	Likert 1-5 (1 = very little extent; 5 = very great extent)	0.80	Haynes *et al* 1999 & Rizzo *et al* 1970	3/3.3
Task proactivity	3	▪ Over the past year how often.. have you initiated better ways of doing your core tasks?	Likert 1-5 (1=very little; 5=a great deal)	0.92	Griffin, Neal & Parker (2007)	3/3.4
Voice	3	▪ How frequently do you.. challenge doctors or other professionals?	Likert 1-5 (1=Never; 5=Always)	0.77	Van Dyne & LePine (1998)	3/3.5
Taking charge	3	▪ How frequently do you.. make suggestions for improvements?	Likert 1-5 (1=Never; 5=Always)	0.85	Morrison & Phelps (1999)	3/3.5
Reflexivity	2	▪ How frequently do you.. reflect on ways you could have done things more effectively?	Likert 1-5 (1=Never; 5=Always)	0.83	Parker, Collins & Johnson (in prep.)	3/3.5
Task performance	3	▪ How frequently do you.. meet performance expectations?	Likert 1-5 (1=Never; 5=All of the time)	0.79	Williams & Anderson (1991)	3/3.5
Anxiety-Contentment	6	▪ During the past month, how much of the time has your job made you feel... tense?	Likert 1-5 (1=Never; 5=All of the time)	0.85	Warr (1990)	3/3.6
Depression-enthusiasm	6	▪ During the past month, how much of the time has your job made you feel...miserable?	Likert 1-5 (1=Never; 5=All of the time)	0.87	Warr (1990)	3/3.6
Work engagement – Vigor	3	▪ At my work, I feel bursting with energy ▪ At my work, I feel strong and vigorous	Likert 0-6 (0=Never; 6=Always)	0.90	Schaufeli, Bakker & Salanova (2006)	3/3.7

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Table 3.1 continued

Variable name	No of items	Example items	Response scale	Reliability	Source	Section/ sub-section
Work engagement - Absorption	3	• I am immersed in my work • I get carried away when I am working	Likert 0-6 (0=Never; 6=Always)	0.80	Schaufeli, Bakker & Salanova (2006)	3/3.7
Job satisfaction	3	• Generally speaking, I am very satisfied with this job • I frequently think of quitting this job	Likert 1-5 (1=strongly disagree; 5 = strongly agree)	0.78	Hackman & Oldham (1975)	3/3.8
Person-organisation fit	3	• My organisation's values and culture provide a good fit with the things I value in life • My personal values match my organisation's values and culture	Likert 1-5 (1=strongly disagree; 5 = strongly agree)	0.93	Cable and DeRue (2002)	3/3.9
Ideological fit with standardised care	4	• Standardised care enables me to work in a manner that is consistent with my ideals of care • Standardised care supports my approach to patient care	Likert 1-5 (1=strongly disagree; 5 = strongly agree)	0.95	Designed for present study drawing on Hunter (2004)	3/3.9
Positive organisational support	3	• My organisation cares about my opinions • My organisation cares about my general satisfaction and well-being at work	Likert 1-5 (1=strongly disagree; 5 = strongly agree)	0.92	Eisenberg, Fasolo and Davis-LaMastro (1990)	3/3.9
Preferences for following procedures	4	• It is not necessary to follow procedures to the letter • Everything is done by the book	Likert 1-5 (1=very undesirable; 5 = very desirable)	0.92	Patterson, West, Shackleton, Dawson, Lawthom, Maitlis, Robinson & Wallace (2005)	3/3.10

3.5 Response rates and sample characteristics

A total of 2,711 web and paper-based responses were received, representing a 21% overall response rate to the survey. From RCN members, 971 responses were returned, from RCM members, 1483 responses were returned representing a 31% response rate to the survey. From CPHVA members, 241 responses were returned representing a 5% response rate. The low response rate from CPHVA members is due to distributional problems with the survey. Initially, the survey was going to be distributed through the CPHVA's Community Practitioner journal. However, for reasons that we were not able to ascertain, the survey was distributed separately, rather than as an inset to the journal, and not all 5,000 copies were sent out.

Table 3.2 presents sample descriptives in relation to professional group, by gender, grade, main work activity, age, tenure and years experience in nursing.

The demographic profile for the whole sample and for each of the three professional groups is presented in Table 3.3. The majority of respondents were female (96.5%) with an average age of 44.57 and their organisational tenure was approximately seven and a half years. The average reported experience in nursing, midwifery and health visiting was approximately 21 years although for the health visiting sample this was slightly above the average for the whole sample (27 years). Most respondents reported that their Agenda for Change Banding was 5 to 7 with only 6.5% of the sample reporting belonging to Bands 8A and above.

Overall, 1565 respondents reported working in NHS Hospitals. Of these 1565, 659 were hospital midwives, 288 were staff nurses, 210 were community midwives, 161 were Sisters/Ward Managers and 141 were Senior Nurses/Midwife Matrons. Of the 364 individuals who worked for NHS Community, the majority were community midwives (162), followed by health visitors (93), community nurses (40), Senior Nurses/Midwife Matrons (13), Clinical Specialists (13) and District Nurses (11). Finally, from the 222 respondents who worked in Primary Care Trusts, 77 were health visitors, 33 were community midwives and nurses and 14 were school nurses.

Table 3.2. Demographic profile of nurses, midwives and health visitors participating in survey

Characteristic	Health professional group			Total
	Nurses	Midwives	Health Visitors	
Gender				
Female	888	1460	237	2585
Male	77	13	2	92
Total	965	1473	239	2677
Agenda for Change Banding				
5-7	777	1373	214	2364
8A-8D	68	77	16	161
9	2	1	0	3
Total	847	1451	230	2528
Type of activity				
Clinical	705	1262	162	2129
Management	130	84	16	230
Education/Teaching	32	40	9	81
Service Development	26	24	12	62
Research	13	7	1	21
Total	1417	906	200	2523
Age[1]	43.76	44.27	49.79	44.57
Organisational tenure	5.87	8.60	8.81	7.63
Years experience in nursing, midwifery or health visiting	20.68	20.34	27.01	21.06

[1]For age, organisational tenure and years experience, mean values are reported for both the whole sample and each of the nursing, midwifery and health visiting sub-samples.

Appendix 3b: Questionnaire

Section 1. What standardised care means to you

There are many different terms used for 'standardised care' including protocols, clinical guidelines, care pathways or algorithms/ flow charts. We are interested in the terms that you use, and what some of these terms mean to you.

1.1 **What do the following terms mean to you?** Please tick the box in each row that best describes what each of these terms means to you.

		A specific task or procedure	A set of procedures or activities that are part of the patient journey	Procedures for overall patient journey	None of these
1.	Protocol	❑	❑	❑	❑
2.	Clinical guideline	❑	❑	❑	❑
3.	Care pathway	❑	❑	❑	❑
4.	Algorithm/flowchart	❑	❑	❑	❑

1.2 **What is your understanding of the status of each form of standardised care?** Please tick the box in each row that best describes your understanding of the status of each form of 'standardised care'.

		Mandatory: required to comply	Advisory: normally comply with	Information: to support your clinical reasoning	None of these
1.	Protocol	❑	❑	❑	❑
2.	Clinical guideline	❑	❑	❑	❑
3.	Care pathway	❑	❑	❑	❑
4.	Algorithm/flowchart	❑	❑	❑	❑

Your views on the impact of 'standardised care' on working practices

1.3 **Thinking generally about the impact of 'standardised care' where you work, to what extent do you agree or disagree with the following?** *Please circle one number in each row*

'Standardised care':	*Strongly disagree*		*Neither agree/nor disagree*		*Strongly agree*
1. Promotes safe treatment/interventions	1	2	3	4	5
2. Helps reduce variation in the quality of care	1	2	3	4	5
3. Provides clarity regarding care standards	1	2	3	4	5
4. Supports clinically effective interventions	1	2	3	4	5
5. Helps make the best use of staff skills and knowledge	1	2	3	4	5
6. Promotes effective multi-disciplinary teamwork	1	2	3	4	5

Use of 'standardised care' in your post

1.4 **What is your field of practice?** *Please tick one box only*

Primary Care	☐	Community Care	☐	Older People Nursing	☐	*Mental Health*	☐	*Adult Critical Care*	☐
Adult General	☐	Rehab/Longer term	☐	Women's Health	☐	Learning Disabilities	☐	Several different fields	☐
Education/ Research	☐	Midwifery	☐	Paediatrics	☐	Oncology/ Palliative care	☐	Child and Family Health/ Childen and Families	☐

Other (please specify): _____

1.5 **How much of your time do you spend providing direct patient care?** *Please circle one number*

Never	*Seldom*	*Some of the time*	*Most of the time*	*All of the time*
1	2	3	4	5

If your answer to Question 1.5 is 'Never', please go to Section 3 on page 4

1.6 Thinking about all the forms of 'standardised care', in the <u>last 2 years</u> to what extent have you: *Please circle on number in each row.*

		Not at all		Moderate extent		Great extent
1.	Led the development of 'standardised care'?	1	2	3	4	5
2.	Helped to develop 'standardised care'?	1	2	3	4	5
3.	Introduced 'standardised care' into practice?	1	2	3	4	5
4.	Used 'standardised care'?	1	2	3	4	5
5.	Updated 'standardised care'?	1	2	3	4	5
6.	Audited the impact of 'standardised care'?	1	2	3	4	5

1.7 To what extent do the following forms of 'standardised care' influence the care that you give? *Please circle on number in each row.*

		Not at all		Moderate extent		Great extent
1.	Protocols	1	2	3	4	5
2.	Clinical guidelines/clinical practice guidance	1	2	3	4	5
3.	Care pathways/integrated care pathways	1	2	3	4	5
4.	Algorithms/decision making trees/flowcharts	1	2	3	4	5

1.8 Of these forms of 'standardised care', please indicate the one which <u>most</u> influences the care that you give. *Please tick one box only*

1.	Protocols	☐	4.	Algorithms/decision making trees/flowcharts	☐
2.	Clinical guidelines/clinical practice guidance	☐	5.	None of these	☐
3.	Care pathways/integrated care pathways	☐	6.	Other (please specify: _____	☐

For the remaining sections of the questionnaire, please answer each question in relation to th for the form 'standardised
 care' that most influences the care that you give

1.9   Overall, how much of your direct patient care involves giving this form of 'standardised care'? *Please circle one number.*

None of my direct care	A little of my direct care	Some of my direct care	Most of my direct care	All of my direct care
1	2	3	4	5

1.10   In your workplace, to what extent is the 'standardised care' that you deliver: *Please circle one number in each row.*

		Very little extent		Moderate extent		Very great extent
1.	Mandatory	1	2	3	4	5
2.	Advisory	1	2	3	4	5
3.	Informative	1	2	3	4	5

1.11   Where 'standardised care' exists in your job, please indicate how much of the time you comply with it? *Please circle 'not applicable' if 'standardised care' does not exist in your job.*

Never	Seldom	Some of the time	Most of the time	All of the time	Not applicable
1	2	3	4	5	6

1.12   Listed below are different aspects of care. How much of the time do you use 'standardised care' when delivering these tasks? *Please circle 'Not applicable' for any aspects of care that you do not deliver*

		Never	Seldom	Some of the time	Most of the time	All of the time	Not applicable
1.	Health screening	1	2	3	4	5	6
2.	Assessment	1	2	3	4	5	6
3.	Intervention or care	1	2	3	4	5	6
4.	Prescribing	1	2	3	4	5	6
5.	Patient education	1	2	3	4	5	6
6.	Discharge	1	2	3	4	5	6
7.	Other (please specify):	1	2	3	4	5	6
	1. _____	1	2	3	4	5	6

Section 2. Your experience of using 'standardised care'

The following questions represent a range of views and experiences in using 'standardised care'. In answering, please think about the form of 'standardised care' that most influences and directs the care that you give.

2.1   Please indicate the extent to which you agree with the following statements regarding your place of work: *Please circle one number in each row.*

In my workplace:	Strongly disagree		Neither agree nor disagree		Strongly agree
1. Staff responsible for hands-on delivery of care are involved in developing 'standardised care'.	1	2	3	4	5
2. Staff involvement in developing 'standardised care' is encouraged where I work	1	2	3	4	5
3. The 'standardised forms of care' are regularly reviewed	1	2	3	4	5
4. Deviations/variances from 'standardised care' are regularly analysed	1	2	3	4	5
5. Deviations/variances from 'standardised care' are seen as learning opportunities	1	2	3	4	5
6. I have the opportunity to suggest improvements to 'standardised care'	1	2	3	4	5
7. I am encouraged to identify ways to improve the 'standardised care' that exists	1	2	3	4	5
8. I know who to approach if I want to submit suggestions for improving 'standardised care'	1	2	3	4	5
9. We have 'standardised care' for every situation	1	2	3	4	5
10. People always follow strict 'standardised care' at all times	1	2	3	4	5
11. People always check to see that they are following 'standardised care' procedures	1	2	3	4	5

2.2   Please indicate to what extent you agree with the following statements: *Please circle one number in each row.*

		Strongly disagree		Neither agree nor disagree		Strongly agree
1.	I clearly understand the rationale behind the 'standardised care' procedures I implement	1	2	3	4	5
2.	I understand why we have 'standardised care' procedures in place	1	2	3	4	5
3.	I am clear about how to follow the 'standardised care' procedures that exist in my job	1	2	3	4	5
4.	I have a good understanding of the 'standardised care' procedures that I am expected to follow	1	2	3	4	5
5.	The 'standardised care' procedures I use in my job are well-designed and make sense	1	2	3	4	5
6.	The 'standardised care' in my work is evidence-based	1	2	3	4	5
7.	If I judge it in the best interests of a specific patient, it is not mandatory to follow 'standardised care' procedures	1	2	3	4	5
8.	In my workplace, it is acceptable to bypass or deviate from 'standardised care' procedures if the situation demands	1	2	3	4	5
9.	I can bypass or deviate from 'standardised care' procedures if I need to without supervisory permission	1	2	3	4	5
10.	I have the freedom to deviate from 'standardised care' procedures if the situation calls for it	1	2	3	4	5
11.	The 'standardised care' procedures we have in place is for management to 'cover their backs'	1	2	3	4	5
12.	The 'standardised care' procedures in my job have been introduced to improve patient care	1	2	3	4	5
13.	I have had sufficient training in the 'standardised care' that I am expected to follow	1	2	3	4	5

2.3 **How frequently do you:** *Please circle one number in each row*

		Never	Rarely	Sometimes	Most of the time	Always
1.	Adopt an approach to care informed by a careful consideration of each patient's needs?	1	2	3	4	5
2.	Use your professional judgment to ensure that the 'standardised care' procedures you use are appropriate for the patient?	1	2	3	4	5
3.	Try to identify an alternative plan of care when 'standardised care' procedures are inappropriate for the patient?	1	2	3	4	5
4.	Deviate from 'standardised care' procedures in order to deliver better patient care?	1	2	3	4	5

Section 3. About you and your job

In this section we would like to find out how you feel about your job as a whole; your views about workload, your role, your ability to make a difference and to get your point across.

3.1 **Please indicate the extent to which you agree with the following statements:** *Please circle one number in each row.*

		Strongly disagree		Neither agree nor disagree		Strongly agree
1.	I have significant autonomy in determining how I do my job	1	2	3	4	5
2.	I can decide on my own how to go about doing my work	1	2	3	4	5
3.	I have considerable opportunity for independence and freedom in how I do my job	1	2	3	4	5

3.2 **Please indicate the extent to which you agree with the following statements:** *Please circle one number in each row.*

		Strongly disagree		Neither agree nor disagree		Strongly agree
1.	I am confident about my ability to do my job	1	2	3	4	5
2.	I am self-assured about my capabilities to perform work activities	1	2	3	4	5
3.	I have mastered the skills necessary for my job	1	2	3	4	5

3.3 **Please indicate the extent to which the following statements apply to your job:** *Please circle one number in each row.*

		Very little extent		Moderate extent		Very great extent

1.	Would you say your work is routine?	1	2	3	4	5
2.	Do people in this unit do about the same job in the same way most of the time?	1	2	3	4	5
3.	Are unit members performing repetitive activities in doing their jobs?	1	2	3	4	5
4.	Is there a clearly known way to do the major types of work you normally encounter?	1	2	3	4	5
5.	Is there an understandable sequence of steps that can be followed in doing your work?	1	2	3	4	5
6.	To do your work, can you actually rely on established procedures and practices?	1	2	3	4	5
7.	Do you work faster than you would like to complete your work?	1	2	3	4	5
8.	Do you have too much work to do in too little time?	1	2	3	4	5
9.	Can you follow best practice in the time available?	1	2	3	4	5
10.	Do youuse a variety of skills?	1	2	3	4	5
11.	Are you challenged by your job?	1	2	3	4	5
12.	Do you have the opportunity to do what you do best?	1	2	3	4	5
13.	Do you know that you have divided your time properly?	1	2	3	4	5
14.	Do you know what your responsibilities are?	1	2	3	4	5
15.	Do you know what is expected of you at work?	1	2	3	4	5
16.	Do you receive conflicting instructions from two or more people?	1	2	3	4	5
17.	Do your colleagues make conflicting demands on you?	1	2	3	4	5
18.	Do you do things that are accepted by one person but not another?	1	2	3	4	5

How do you feel about your work

The first set of questions concern how you are able to carry out your job. Please rate what you actually do, not what you think you 'should' do. The questions that follow address how your work, as a whole, affects you.

3.4   How often have you carried out the following behaviours over the past <u>year</u>? *Please circle on number in each row.*

		Very little				A great deal
1.	Initiated better ways of doing your core tasks	1	2	3	4	5
2.	Come up with ideas to improve the way in which your core tasks are done	1	2	3	4	5
3.	Made changes to the way your core tasks are done	1	2	3	4	5

3.5   How frequently do you: *Please circle one number in each row*

		Never	Rarely	Sometimes	Often	Always
1.	Challenge doctors or other professionals?	1	2	3	4	5
2.	Speak out firmly on behalf of patients when it would help the situation?	1	2	3	4	5
3.	Voice your concerns when you perceive a problem with patient care?	1	2	3	4	5
4.	Make suggestions for improvements?	1	2	3	4	5
5.	Challenge or question traditional ways of doing things?	1	2	3	4	5
6.	Try to bring improved procedures in your workplace?	1	2	3	4	5
7.	Reflect on ways you could have done things more effectively?	1	2	3	4	5
8.	Take time to consider how you might have dealt with a situation differently?	1	2	3	4	5
9.	Meet performance expectations?	1	2	3	4	5
10.	Provide quality patient care?	1	2	3	4	5
11.	Provide timely patient care?	1	2	3	4	5

3.6   During the <u>past month</u> how much of the time has your job made you feel: *Please circle one number in each row.*

		Never	Occasionally	Some of the time	Most of the time	All of the time
1.	Tense	1	2	3	4	5
2.	Miserable	1	2	3	4	5
3.	Depressed	1	2	3	4	5
4.	Optimistic	1	2	3	4	5
5.	Calm	1	2	3	4	5
6.	Relaxed	1	2	3	4	5
7.	Worried	1	2	3	4	5
8.	Enthusiastic	1	2	3	4	5
9.	Anxious	1	2	3	4	5
10.	Comfortable	1	2	3	4	5
11.	Gloomy	1	2	3	4	5
12.	Motivated	1	2	3	4	5

3.7   Please read each statement and decide if you ever feel this way about your job: *Please circle one number in each row.*

		Never	Almost never *(a few times a year or less)*	Rarely *(once a month or less)*	Sometimes *(a few times a month)*	Often *(once a week)*	Very often *(a few times a week)*	Always *(every day)*
1.	At my work, I feel bursting with energy	1	2	3	4	5	6	7
2.	At my job, I feel strong and vigorous	1	2	3	4	5	6	7
3.	I am enthusiastic about my job	1	2	3	4	5	6	7
4.	My job inspires me	1	2	3	4	5	6	7
5.	When I get up in the morning, I feel like going to work	1	2	3	4	5	6	7

6.	I feel happy when I am working intensely	1	2	3	4	5	6	7
7.	I am proud of the work that I do	1	2	3	4	5	6	7
8.	I am immersed in my work	1	2	3	4	5	6	7
9.	I get carried away when I am working	1	2	3	4	5	6	7

3.8   Please indicate the extent to which you agree with the following statements: *Please circle on number in each row.*

		Strongly disagree		Neither agree nor disagree		Strongly agree
1.	Generally speaking, I am very satisfied with this job	1	2	3	4	5
2.	I frequently think of quitting this job	1	2	3	4	5
3.	I am generally satisfied with the kind of work I do on this job	1	2	3	4	5

What you think about your organisation

In this section we are interested in how much you identify with the values of the organisation in which you work and how much you feel that your organisation supports you in all areas of your work. In answering this section, please assume that each question applies to the organisational unit most relevant to you.

3.9   Please indicate to what extent you agree with the following statements: *Please circle one number in each row.*

		Strongly disagree		Neither agree nor disagree		Strongly agree
1.	My organisation's values and culture provide a good fit with the things I value in life	1	2	3	4	5
2.	The things I value in life are very similar to the things that my organisation values	1	2	3	4	5
3.	My personal values match my organisation's values and culture	1	2	3	4	5
4.	'Standardised care' enables me to work in a manner that is consistent with my ideals of care	1	2	3	4	5
5.	'Standardised care' supports my approach to patient care	1	2	3	4	5
6.	'Standardised care' enables me to retain my ideals of good patient care	1	2	3	4	5
7.	'Standardised care' provides a good fit with my approach to patient care	1	2	3	4	5
8.	My organisation cares about my general satisfaction and well-	1	2	3	4	5

	being at work					
9.	My organisation cares about my opinions	1	2	3	4	5
10	My organisation is willing to extend itself in order to help me perform my job to the best of my ability	1	2	3	4	5

Your personal preferences at work

We are not all alike. We are interested in your personal preferences in your approach to work and the types of work environments that you find desirable.

3.10   **How *desirable* is it for <u>you</u> to work in an organisation where:** *Please circle on number in each row.*

		Very undesirable		Neither desirable nor undesirable		Very desirable
1.	People can ignore formal procedures and rules if it helps get the job done	1	2	3	4	5
2.	It is not necessary to follow procedures to the letter	1	2	3	4	5
3.	Everything is done by the book	1	2	3	4	5
4.	It is considered extremely important to follow the rules	1	2	3	4	5

Section 4. About you and where you work

This section asks for information about your background. This is so we can understand the settings where different types of standardised care have been introduced.

4.1   **How old are you?** _____ **years**   **4.2**   **Are you male or female?**   ❑ **male**   ❑ **female**

4.3   **How many years experience have you got in nursing, midwifery or health visiting?** _____ **years**

4.4   **Which part/s of the Nursing and Midwifery Register are you on?**

		Yes	No
1.	Nursing	❑	❑
2.	Midwifery	❑	❑
3.	Specialist Community Public Health Nursing	❑	❑

Your current role

4.5   **Which type of employer do you work for?** *Please tick one box only.*

NHS Hospital	☐	NHS Community	☐	NHS Direct	☐	NHS Other	☐
GP Practice	☐	Independent Hospital	☐	Care Home	☐	Other Independent	☐
Bank/Agency	☐	Higher Education	☐	Hospice/Charity	☐	School	☐
Health Authority/NHS Executive	☐	Other Health Employer	☐	Primary Care Trust	☐	Other (please specify): _____	☐

4.6 **What is your current job title?** *Please tick one box only*

Staff Nurse	☐	Community Nurse	☐	Community Midwife	☐	Sister/Ward Manager/ Charge Nurse	☐	Practice Nurse	☐
District Nurse	☐	School Nurse	☐	Nurse Practitioner	☐	Senior Nurse or Midwife Matron /Manager	☐	Hospital Midwife	☐
Health Visitor	☐	Manager/ Director	☐	Researcher/ Lecturer	☐	Clinical Specialist/ Consultant	☐	Other (please specify): _____	

4.7 **How long have you worked in your current post?**   _____ years   _____ months

4.8 **Of these forms of 'standardised care', please indicate the one which <u>most</u> influences the care that you give.** *Please tick one box only*

5	☐	6	☐	7	☐	8A	☐	8B	☐	8C	☐	8D	☐	9	☐	Other	☐

4.9 **How many staff do you directly supervise or manage?**   _____   *If none, but o*

4.10 **On a 'typical day', what do you spend most time doing?** *Please tick one box only.*

Clinical Activities	Management	Education/Teaching	Service Development	Research	Other
☐	☐	☐	☐	☐	☐

Any other comments?

If you would like to make any further comments about your experience of, or feelings about using 'standardised care', such as protocols, pathways or guidelines, please do so in the space below and continue on a separate sheet. Please use capital letters to help us read your writing. Remember not to include any details that may identify you or your employer. We will screen what you write and remove any potentially identifying information when we analyse your verbatim comments.

Thank you so much for taking the time to complete this questionnaire. Your contribution will help us understand how nurses, midwives and specialist community public health nurses are coping with a major change in health and social care delivery.

Now, please return the completed form in the stamped addressed envelope to:

Dr. Chrysanthi Lekka, Institute of Work Psychology, University of Sheffield, Mushroom Lane, SHEFFIELD, S10 1BQ

Appendix 4a: Method - Case studies

4.1 Criteria for inclusion of sites

The five case studies were chosen to show the different ways in which nurses, midwives and health visitors contribute towards the development, implementation and audit of standardised care and to examine the impact of standardised care on staff, patient and economic outcomes. In order to achieve this, the selection of case studies met the following criteria:

▪ Sites were about to or had recently implemented some form of standardised care, and/or had a well-established form of standardised care in place that was extensively used by nurses, midwives and health visitors and had gone through the cycles of development, implementation, audit and review.

▪ Different types of standardised care had been developed and nurses, midwives or health visitors had played a key role in the development and implementation of standardised care. Development may have been bottom-up in response to a local need or top-down by locally adapting a national guideline.

▪ Sites reflected a variety of settings such as Primary Care Trusts, a teaching Primary Care Trust, a teaching hospital and a district general hospital.

Initially 20 sites were identified opportunistically based on the team's and expert panel's personal contacts. In some cases, support from professional bodies helped identify appropriate sites. For instance, one of the nursing case study sites was recruited through the Community Practitioners' and Health Visitors' Association maternal depression network that advertised a call about the research.

4.2 Procedure and methods

The case studies were exploratory in nature and a number of data collection methods were used. These included semi-structured interviews, focus groups, observations and document analysis. The combination of methods used was negotiated with each individual case study site. Specifically, meetings were held with staff from each case study site in order to agree the research questions and the data collection methods that would be feasible and acceptable within each site.

In each of the case study sites, research was conducted on the Trust or macro and the individual or micro level. At the macro level, research focused on gathering evidence regarding strategic level issues associated with the introduction, development, implementation and use of standardised care within each Trust. These included:

▪ Reasons behind the introduction and support for standardised care within the Trust.

- Mechanisms in place for the development, implementation, audit and review of standardised care as well as identification of barriers and success factors associated with each of these stages.

- How extensively standardised care is used within each Trust and any variations observed across different groups and/or specialisms.

- Future strategies regarding the development of standardised care within each Trust.

At the micro level, research focused on gathering evidence regarding the contribution of nursing, midwifery and health visiting staff to the development, implementation and audit of standardised care and its perceived impact on patient and staff outcomes. Specific issues addressed at the micro level included:

- Roles adopted by nurses, midwives and health visitors during each of the development, implementation and review stages of standardised care.

- Barriers and success factors contributing to the development, implementation and review of standardised care.

- Use of standardised care as part of daily work and identification of barriers and challenges in use and long-term sustainability.

- Impact of standardised care on staff (e.g. professional autonomy, learning and skill use) and patient outcomes (e.g. quality of care).

In order to obtain a macro level perspective on standardised care, a number of strategic interviews were carried out with senior managers at each site. For the micro level perspective, interviews and focus groups were carried out with the operational leads and front-line staff at each of the case study sites. Development group meetings were also observed. Although the focus at each case study differed (e.g. in terms of the type of standardised care used; local circumstances around the introduction, development and implementation of standardised care), by focusing on broad macro and micro level issues it was possible to compare findings across sites and thus identify commonalities and differences.

In all cases, key contacts at each of the case study sites were asked to identify individuals that the research team could approach for an interview or focus group. All potential participants were subsequently sent an invitation letter, a participant and case study information sheet and a consent form.

Appendix 4b: Interview guides
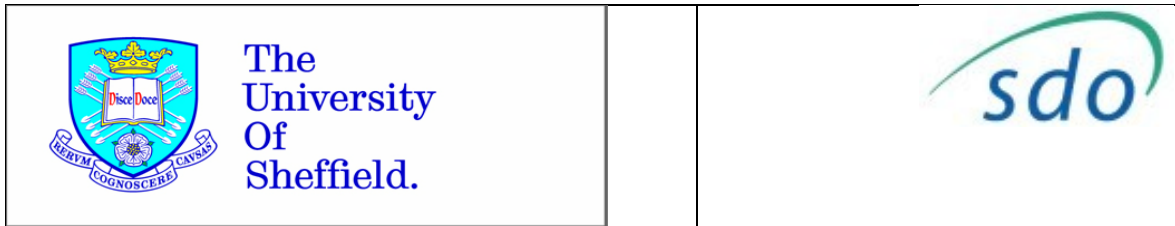
**STANDARDISING CARE AND
ITS IMPACT ON THE QUALITY OF WORKING LIVES**

INTERVIEW GUIDE FOR SENIOR MANAGERS

Indicative questions for semi structured interviews with a purposive sample of senior managers in [name of Trust].

Interviewees to include Chief Executive and Director of Nursing Services to address strategic issues and opinions.

1. **Background**: about self, *including role, professional group and qualifications, grade, professional background, length in current post*

2. **What** forms of 'standardised care' such as protocols, clinical guidelines and care pathways are used within this Trust?   Do you know where and how extensively are they used?

3. **Why** – what are the strategic reasons for promoting and supporting 'standardised care' within this Trust? *e.g. national standards, quality initiatives, costs, risk management*

4. **What** mechanisms have been established/are in place for developing, introducing, using, auditing and sustaining 'standardised care' within the Trust?

5. **Opinions** and observations about any differences noted about where used/accepted and where less so such as between *services, professions or specialities.*

6. **Impact** – observations about any difference that using 'standardised care' may or not make to patients (*complaints, length of stay, quality of care, patient satisfaction*), staff (*satisfaction, turnover, recruitment and retention*) and the organisation (*costs, reputation, risk management)*

7. **Lessons learned** from experience about the barriers and success factors that help 'use in practice' and sustainability 'over time.'

8. **Future** strategy/plans for 'standardised care' in the context of the changes in NHS.

9. **Any other comments?**

Appendix 4b continued	
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STANDARDISING CARE AND
ITS IMPACT ON THE QUALITY OF WORKING LIVES
INTERVIEW GUIDE FOR USERS

Indicative questions for semi structured interviews with a purposive sample of the staff at [name of Trust] who use, or may not use, the MI care pathway when caring for patients who have had a myocardial infarction. Staff includes nurses, health visitors, medical practitioners and other members of the multi-disciplinary team.

The questions are intended to draw upon the direct experience of staff through the use of specific examples.

1. **Background**: about self

2. **Beliefs** about how care pathways should be used both in your work and in the context of other health professionals' work

3. **Reasons** behind the introduction of pathways and the mechanisms in place for their implementation, audit and annual review

4. **General experience**– whether tend to use or not the care pathway with MI patients.

5. **Specific examples** of using and not using the MI integrated care pathway

6. **Potential challenges** or difficulties in using care pathways and factors that may affect their effectiveness and/or ineffectiveness

7. **Barriers and success factors** that help 'use in practice' and sustainability of 'standardised care' in the long-term.

Please note: Patient confidentiality and anonymity will be stressed when discussing the examples. All the recording will be screened for patient identifiable information, and this will be removed before the records are sent for transcription.

Appendix 4c: Nursing case study 1: Implementation - Liverpool Care Pathway (LCP)

4.1 Organisational context

This nursing case study describes the implementation and roll-out of the Liverpool Care Pathway (LCP) throughout a district general hospital in central England. The LCP is an evidence-based framework for end of life care and translates best practice for care of the dying from the hospice into other care settings. The pathway aspires to deliver high quality care to dying patients by providing a standardised and proactive plan for end of life care, which includes symptom control to optimise patient comfort, and psychosocial and spiritual support as well as bereavement care. The LCP is initiated when the professional team members agree that a patient is in the dying phase. It is split into three broad sections: initial assessment and care, ongoing care (physical, psychological and spiritual), and care after death. The LCP is a key recommendation in the NICE guidelines for supportive and palliative care and the End of Life Care Strategy (DH 2008).

4.2 Aims and methods of the case study

The case study explored the stages undertaken for the introduction, 'ownership' and implementation of the care pathway within the hospital, and also nurses' experiences and attitudes towards the LCP. The case study also identified factors that may facilitate or hinder the care pathway's sustainability in the long-term. Finally, insight was also gained on the impact the LCP has on nurses' feelings of competence and the quality of patient care they provide.

Data was collected through semi-structured interviews with the following members of staff:

- Four palliative care team (PCT) members

- Consultant

- Staff nurse acting as a link nurse for the PCT

4.3 Development and implementation of the LCP

Table 4.2 shows the stages involved in the introduction of the LCP, its key advantages, and factors that facilitate and hinder its adoption and maintenance. The table draws on elements of Greenhalgh *et al*.'s framework on the spread and sustainability of innovations.

The case study site was an acute hospital and one of the early implementer sites of the Liverpool Care Pathway. Adoption of the LCP was instigated by two nurses, the Palliative

Care Team Leader and the Lead Cancer Nurse. The pathway was initially piloted for a year in the oncology wards, and data gathered both before and after its introduction revealed improvements in the quality of care provided. The successful piloting of the LCP was subsequently followed by Trust Board approval for the LCP to be rolled-out to all wards in the hospital. Agreement was also obtained from all the Trust consultants although there was little evidence to indicate that they were actively involved in its adoption. Funding for a 3-year period was secured from the MacMillan Cancer Support charity, commencing in April 2005, to employ a LCP coordinator to lead the implementation of the pathway. The care pathway has now been rolled out onto a further eight wards, including acute medical, surgical and emergency assessment wards. The aim was to introduce the LCP to the remaining wards over the next 18 months.

There is no doubt that rolling out the LCP was a time-consuming and quite an arduous process. Implementation was driven by the LCP coordinator but with considerable support from the Palliative Care Team. Both provided training for staff as it was introduced to a ward. They also provided on-going support to staff to educate, guide, and reassure them in the use of the pathway. Each ward had a link nurse acting as a link to the PCT and as a champion for the LCP. However, despite a careful, methodical approach to implementation, a coordinator dedicated to its introduction and use, and the support of a committed PCT, the response to the LCP across the hospital was variable and sustaining its use was a challenge. Although there were wards that embraced the LCP, there are many cases of patients identified as dying but not placed on the LCP, and some wards proved quite resistant to its adoption. Reasons for the variable adoption of the LCP are discussed below but it was clear that the interviewees felt that the LCP was beneficial to staff, patients and their carers. However, a note of caution is necessary when considering the relative advantages and disadvantages of the LCP. The interviewees in this case study were all to some degree involved in promoting the use of the LCP and therefore their views did echo their enthusiasm for the pathway. However, many of the interviewees had spent a considerable amount of time implementing the LCP and attempting to sustain its use, and consequently were able to offer considerable insight into the issues surrounding its uptake and the different meanings attached to the pathway

4.4 Impact and challenges to implementation and sustainability

This section explores the main themes that emerged from the interviews, discussing the ways that the Liverpool Care Pathway has impacted on both staff and patients and the key challenges identified to its implementation and sustainability.

On the whole, the LCP was compatible with staffs' values relating to end of life care, reflecting a desire to provide effective evidence-based care during a sensitive and difficult time. Several benefits were identified for staff. The pathway was largely seen as empowering; a tool that provides nursing staff with comprehensive guidelines on palliative care and promoted procedural and role clarity, and provided support when discussing a patient's needs with clinicians. It was generally thought to instil confidence in care provision and promote greater involvement in decision-making. The pathway also provides documented evidence of the quality of care delivered.

Table 4.1. Key features in the development and implementation of LCP

Development	Implementation and Sustainability
Policy Context: • £12m over three years was allocated at the end of 2003 by DOH to help promote implementation of best practice in end of life care. A key tool for achieving this is the Liverpool Care Pathway (LCP) – taking the best of hospice care such as good communication with patients and their families and symptom control. **Organisational Context**: • Improving quality, consistency and documentation of end of life care. **Features of Standardised Care**: *Relative advantage* • Supports staff with guidance, tools and skills to provide effective, evidence-based, end of life care. • Seeks to provide joined up practice for MDT caring for the patient. *Compatibility* • Mostly compatible with values and needs of staff. • However, some incompatibility exists with the beliefs of some staff who see it as 'a death sentence' or a form of euthanasia and believe their role is to 'cure'. • Some staff, especially consultants, do not see clear advantages to the LCP, which inhibit the pathways take-up. *Complexity* • Fairly straightforward intervention that does not need major changes in ways of working, although investment in education and training required.	**Adoption:** *Meaning* ▪ Most users see LCP as a valuable tool for providing effective care. ▪ For some, 'paperwork', 'unnecessary interference', 'a death sentence'. *Nature of adoption decision* ▪ Approval from senior management and consultants, but little consultation – 'this is what we want to do – any comments?' **Adoption and Early use:** *Launch* • Piloted on oncology/haematology ward and then introduced ward by ward by the LCP co-ordinator. *Early concerns* • Availability of nurses for training. • Some see it as an onerous paperwork exercise. • Uncertainty about when a patient should be put on LCP and lack of acknowledgement that a patient is dying – an emotive issue. **Communication and Influence:** • Training sessions provided on each ward by PCT and co-ordinator. • Developed standard education packs to use with all staff. • PCT and coordinator help to identify patients ready for the LCP and ensure the LCP is being used properly. Informal ward training to empower nurses to use pathway. • Link nurses on each ward acting as a link to the PCT and a champion for the LCP. • Teach foundation year doctors about the LCP as part of their induction to the Trust.

Table 4.1 continued

Development Process:

Initiation
- Palliative care team (PCT) leader and lead cancer nurse became aware of LCP, attended a course on LCP and instigated it within the Hospital.
- Conducted a baseline review of end of life care in early 2002 and implemented a pilot on one ward supported by short-term funding.

Facilitation
- Appointed an LCP co-ordinator, backed by the PCT providing teaching and support.
- Co-ordinator post received three-year funding from Macmillan Cancer Support, which started in April 2005.
- Coordinator responsible for implementation, raising awareness, training and advice.

Commitment and Influence
- PCT and LCP co-ordinator are champions for the care pathway, however their power is limited. Commitment required from ward managers and consultants but this is variable.
- Sanctioned but not prioritised at board level.

- LCP more likely to be embraced on wards where is supported by the ward manager and consultants. Strong leadership is vital.

Mechanisms in place for audit and review
- Some auditing has been carried out, looking at adherence to pathway, education needs and potential for improvement. More auditing planned in the future.

Challenges to Implementation and Sustainability
- Slow progress in rolling out and sustaining the LCP on wards, with variable response across wards. Not part of routine practice on some wards.
- Problems of consultant and doctor engagement – seen as a nursing document, imposition on their clinical autonomy, and sits uncomfortably with their professional identity.
- Difficult to embed as doctors rotate every few months, and movement of nursing staff.
- Resistance to using LCP due to difficulty in accepting that a patient is dying and other value and belief based judgements about dying and death, such as whether anyone has the right to declare a 'death sentence'.
- Concern that the patient will not receive personalised care.
- Three year funding of co-ordinator post ended, but appointing new facilitator
  role – seen as vital for spread and embedding of LCP. Dedicated resource required to implement and maintain the pathway.

Interviewees believed the pathway to be extremely beneficial to patients, ensuring evidence-based, holistic end of life care, encompassing every aspect of care provision: physical, psychological, social and spiritual. The pathway helped maintain patient dignity. Physical aspects of care, such as symptom control, pain management and mouth care, were thought to be improved through the use of the pathway. It also cut down on unnecessary interventions that may otherwise increase discomfort and suffering, giving family and patient more time together. However, one interviewee noted that placing a patient on the LCP does not always result in good care. The care can still be substandard if staff routinely fill in the LCP paperwork but give little thought to their care.

Although the interviewees themselves were positive about, and committed to, the use of the pathway, they acknowledged clear concerns from some other users, as well as some other challenges that hindered implementation and sustainability.

Interviewees recognised that the implementation of a pathway for end of life care raised many emotional and moral issues for staff relating to cultural and individual beliefs and values about dying. For example, for some staff, placing a patient on the LCP felt like '*giving up*' on that person and the patient is then '*doomed to die*' simply because they are on the pathway; or that no-one has the right to declare a '*death sentence*' upon any individual; and some see it a form of euthanasia. But even when staff felt comfortable with the aims of the LCP, there could still be a sense of failure and distress when the LCP was initiated. In fact, participants made references to labels sometimes attached to them, such as '*the grim reaper*' and the '*death squad*', indicating that these issues are indeed highly salient for staff.

The decision to place a patient on the LCP was a multi-disciplinary one, however, interviewees recognised that there was often disjointed care due to different beliefs between doctors and nurses. For some doctors, placing a patient on the LCP sits uncomfortably with beliefs and values about their own identity and the purpose of their work – to treat and cure. This sometimes resulted in situations where '*nurses think we should be stepping back and the doctors think we should be pressing on*'. The LCP can be helpful in overcoming these different approaches by signalling a shift in emphasis in the patient's care, so that both doctors and nurses '*are singing from the same song sheet*', however these differences can also result in patchy, inconsistent use of the LCP. This point was illustrated by two interviewees;

> '*I know we had a problem, one where a nurse said to a doctor – don't you think we should put this patient on the pathway and his response was an inappropriate remark, he said 'What do you want to do, kill her?'*

> '*Medically, it is seen as a nursing document. The idea is that the LCP replaces all notes – medical and nursing – they become multi-disciplinary; but sometimes the doctors continue to write their notes because they don't see the LCP as to do with them. Perhaps because they don't understand it, haven't had training, are not interested or because they don't see it as part of their role. Dying is not very sexy is it? It is the failure end of medicine for doctors. A lot of the quality is in the nursing care – they recognise the signs and give the drugs.*'

On a similar note some interviewees felt that such different perspectives on the use of the LCP extended to cultural differences between wards. So, for example, surgical wards, where there was a strong emphasis on cure and discharge, may be less likely to embrace the LCP compared with oncology wards.

Patients can - and have - been removed from the pathway where appropriate as some patients have unpredictable courses. Nevertheless, the interviews revealed that there was suspicion and anxiety surrounding the use of the pathway, suggesting that for some staff the LCP was not seen as a tool that allowed deviation. Some staff viewed the decision to put patients on the pathway as one that can't be undone, and one that did not justify the consequences of making the wrong choice. It was clear that staff often relied on the PCT and pathway coordinator to assist with the decision process.

The LCP provokes inevitable concern over the loss of individualised care. Some interviewees reported that some staff objected to the pathway due to the belief that it depersonalises care and treats the dying process as homogenous, although the interviewees felt that in fact the opposite was true. End of life care leads to many ethical dilemmas, for example whether certain medical treatment should cease because the patient is dying. However, the pathway aimed to manage any patient suffering, and empower nurses to discuss the best course of action with a doctor or a patient's relatives. The interviewees felt that discretion was encouraged and the pathway was open to assessment and discussion, but they recognised that some staff had concerns about stifling individualised care.

The interviewees felt that a facilitator was key to the implementation and sustainability of the LCP. Funding for the original coordinator position had recently ceased. The burden of pushing the LCP forward and training staff fell on the PCT, which they felt was unsustainable on top of their clinical duties. Funding for a part-time facilitator was recently obtained, which was felt by many of the interviewees to be vital for the survival of the pathway.

Leadership was identified as a significant issue. Where the pathway was enthusiastically and proactively adopted by key figures, such as nurse managers and consultants, then this had a real impact on its adoption, and considerably less intervention was required from the palliative care team –

> 'getting the leadership right is the key. Getting consultant engagement and from the senior nurses, then everything else follows. If they lead – 'we're going to start' – then everyone else follows'.

However, consultant engagement was felt to be very mixed and 'without proper consultant engagement it won't sustain itself'. Various reasons were offered for consultants' suspicion or indifference towards the LCP, such as perceiving it as a challenge to their management of dying patients, or perceiving little relative advantage in the pathway. Another possible explanation relates to ownership as there was little attempt to obtain consultant engagement at the beginning of the process.

Other reasons were given for the LCP's variable use more generally. Some staff saw it as onerous additional paperwork that added to their workload. There was also the ongoing challenge of raising awareness and providing staff training among new nursing and clinical

staff in the context of restructuring, staff turnover and movement. Although training sessions over a week or more were key to the introduction of the PCT on each ward, access to all ward staff for training purposes was difficult.

The case study explored the introduction and implementation of the Liverpool Care Pathway within a hospital setting and the experiences and attitudes of its users within the palliative care team, identifying challenges to long-term sustainability. Several factors emerged that were key to the adoption of the pathway:

- **Meaning of the LCP**: The meaning that the LCP held for staff clearly had a strong influence on the uptake of the pathway. For some staff placing a patient on the LCP rubbed up against their beliefs, values, and identity. For example, managing death is difficult in an environment where the emphasis is on cure and it can be difficult to switch from providing curative measures to caring for a dying patient. Consequently using the LCP was, in some cases, associated with failure. The meaning attached to the pathway requires some reframing so there is a shared belief that the LCP supports and ensures good end-of-life care. This extends to beliefs that the pathway supports individualised care and is to be used flexibly.

- **Multidisciplinary care**: Related to the importance of the meaning attached to the LCP was the view, not uncommon in the standardised care literature, that some doctors saw the LCP as a nursing document. Again, establishing shared understanding is important for multi-disciplinary end-of life care.

- **Training, education and audit**: Nurses and doctors may feel unprepared to deal with end-of life care. Training and education in end-of-life care and the use of the LCP is vital to the uptake and sustainability of the LCP, not only to ensure its correct use but also in overcoming concerns and anxieties of users, and establishing the pathways benefits. Also, training must be ongoing to accommodate staff turnover and movement. Further auditing and feedback may also help support the pathway

- **Importance of LCP facilitator**: The importance of a champion leading the introduction and maintenance of the pathway was very apparent. The adoption of the LCP by staff and wards was variable and the continued employment of a full-time facilitator with the back up of the palliative care team is key to its ongoing roll-out and continued use, both in terms of awareness and training. Ready availability of support and advice for staff using the LCP is essential.

- **Consultant and senior nurse support**: Consultant and senior nurse support help drive the successful adoption of the pathway. They have particular influence on the beliefs and actions of those who work with them, and showing indifference to the LCP can be enough to inhibit its spread. Their support, especially consultant buy-in, has been mixed. So getting consultant and senior nurse involvement and commitment is critical to embedding the LCP. Interventions aimed at harnessing the influence of these key individuals will likely enhance the success of the LCP.

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- **Top management support**: It is understandable that the LCP may lose momentum in the face of other Trust priorities such as restructuring, waiting lists, deep cleaning and curative treatments. Senior management support and advocacy of end-of life care will contribute to success in implementing and sustaining the LCP.

Appendix 4d: Nursing Case Study 2. Integrated care pathway for myocardial infarction

4.1 Organisational Context

The care pathway for myocardial infarction (MI) was developed within a District General Hospital in the north of England. The Trust was established in 2002 following the merger with partner organisations, and it became a Foundation Trust in 2005. This is one of two nursing case studies.

4.2 The Integrated Care Pathway in this setting

The nursing case study focuses on a well-established care pathway which provides guidance for the treatment and care of patients with myocardial infarction (MI). The care pathway is a locally developed innovation that has gone through the stages of development, implementation, audit and review. It has been used consistently since 1999 and it is reviewed annually. It was developed in response to the National Health Service (NHS) plan and the National Service Framework (NSF) for Coronary Heart Disease which outlined the need for agreed protocols or systems of care in the assessment and treatment of patients admitted to hospital with confirmed myocardial infarction.

Further, informant interviews revealed that the reason behind the introduction of the care pathway was the identification that there was not a consistent approach to the treatment of cardiac patients at different wards within the hospital. In light of this, the objectives behind the MI care pathway were to standardise patient care across all wards within the hospital and provide a tool that would guide both medical and nursing staff. It should also be mentioned that the initial scope of the pathway was that it would be used at different stages of the patient's 'journey'; that is, from admission to the Accident and Emergency department, transfer to the Coronary Care Unit (CCU) or acute wards for medical treatment and nursing care all the way through to cardiac rehabilitation and discharge home and continued care in primary care. However, lack of sufficient commitment from primary care staff meant that the care pathway has not yet been extended in primary care.

4.3 Aims and methods of case study

This case study focused on exploring the key stages of development and implementation of the MI care pathway and the factors that have contributed to its success and its integration in routine practice within the organisation. Specifically, the stages that took place during the pathway's development and implementation as well as the key individuals involved were identified (Table 4.3). The table draws on Greenhalgh *et al*'s (2004) work on the spread and sustainability of innovations. The case study also aimed to identify the ways that the MI care

pathway has changed clinical practice as well as its impact on patient and organisational outcomes (as perceived by staff).

The following sections summarise the key themes that emerged regarding the above issues from hospital documents as well as seven interviews with staff who occupied different roles within the organisation. The seven interviewees were:

- Two operational leads responsible for instigating and leading the development of the care pathway

- Three nurses using the care pathway

- A strategic manager holding a commissioning role within the Trust

- A Nursing Director

Informants also had varied degrees of involvement in the development and implementation of the pathway. Thus, the interviews offered a diverse perspective on the pathway as well as on standardised care in general within the Trust. The next section presents the key stages and processes of the development and implementation of the MI care pathway. The final section discusses the impact of the MI care pathway – from the informants' perspectives – on staff, patient and organisational outcomes.

4.4 Development and implementation of MI care pathway

Table 4.3 outlines the stages that took place in the development and implementation of the MI care pathway, the defining features of this type of standardised care and key issues that pertain to the use, implementation and sustainability of the care pathway in this setting.

Information regarding the development and implementation of the pathway was obtained from interviews with informants and from hospital documents. In what follows, an outline is provided regarding the key issues pertaining to the development and implementation of the pathway that complements the information presented in Table 4.3.

As mentioned, the care pathway for myocardial infarction is a locally developed innovation initiated in 1999 by a lead cardiologist and a staff nurse. It was developed by a multi-disciplinary team comprising several working groups focusing on different aspects of the patient's journey (e.g. acute and secondary prevention working groups).

Two actions were taken that facilitated the development of the care pathway. First, a one-day stakeholder event was held in April 2000 which was attended by approximately 60 delegates representing primary and secondary care as well as community and support services. This event helped initiate the development process and secure commitment for the MI care pathway. For instance, an outcome of the stakeholder event was the formation of a Pathway Development Team (PDT) which was responsible for overseeing the development, implementation and evaluation of the pathway and 'ensuring that the momentum is maintained'. Second, an ICP-facilitator was appointed to lead the development process by liaising with and offering support to the various working groups.

The MI care pathway took approximately two years to develop and was initially piloted in the Coronary Care Unit and Cardiology ward. The piloting phase was evaluated over a 3-month period and involved an examination of patient records in order to ascertain how the variances (e.g. events that are different to those predicted on the pathway) were recorded as well as obtaining feedback from staff regarding their experiences of using the care pathway.

Table 4.2. Key features in the development and implementation of MI care pathway

Development	Implementation & Sustainability
Policy Context: ▪ National Service Framework for Coronary Heart Disease ▪ Climate of increasing accountability, reducing variations in standards of care delivery and risk management (e.g. NHS Plan, 1999) **Organisational context:** ▪ Reducing variations in treatment of cardiac patients across all hospital wards and ensuring that same standards of care delivered at all times (e.g. weekends, out-of-hours) **Features of standardised care:** *Relative advantage:* ▪ Potential advantage high for members of multidisciplinary team as it provides a systematic and consistent approach to care especially for newly qualified staff ▪ Provides a tool for ensuring nothing is missed and clarity regarding tasks that need to be completed ▪ Reduction in documentation and duplication of information as only one set of records needed and signed by multidisciplinary team ▪ Works best when treatment can follow a well-defined, predictable plan of care ▪ Encourages 'reflective practice' as staff become more aware of what should happen at each stage	**Adoption:** *Meaning:* ▪ For majority ICP as guidance to ensure all aspects of care were delivered in a standardised manner ▪ For minority ICP considered as extra workload because of additional ICP documentation *Nature of adoption decision:* ▪ Collective decision by core development team comprising senior clinicians, managers, cardiac rehab co-ordinator and nurse **Adoption and early use:** *Launch* ▪ Care pathway first piloted on the Coronary Care Unit and Cardiology ward in 2000 ▪ Evaluation of 3-month pilot phase showed staff were positive about the ICP and consequently rolled out to General Medical Unit. ▪ Pathway reviewed and re-launched: 'publicised' ICP with informal presentations and encouraging discussions with staff on how to use it. *Early concerns* ▪ ICP new concept at the time and problems with documentation and recording variances (deviations from ICP) – required less information and staff feeling unsure and 'not safe' ▪ Staff unsure as to how the ICP could be used flexibly with patients that did not have a straightforward recovery

Table 4.2 continued

Compatibility
- Importance of delivering best practice, standards of care and efficiency

Complexity
- Complex to develop and implement as it requires good communication across the primary-secondary interface and high levels of commitment from all members of multi-disciplinary team involved at different stages of the cardiac patient's journey

Time consuming as it spans different care sectors

Development process:

Initiation
ICP as a local development instigated by senior clinician – first ICP developed in the hospital

- One-day stakeholder event was held in April 2000 bringing together staff

  that are involved in different stages of the patient's 'journey' including representatives from both primary care and secondary care; objective to provide an introduction to ICPs, initiate the development process and secure commitment for MI care pathway

- *Facilitation*
Nurse appointed as ICP co-ordinator responsible for leading the development of the pathway:
  - Providing administrative support and liaising with different working parties
  - Responsible for raising awareness and providing training
  - Leading role in audit and review of pathway such as coordinating consultation and feedback processes and re-drafting ICP documentation

- Extra paperwork as nursing staff have to input their care planning on computer and complete pathway documentation

Communication and influence
- Senior clinicians and nurses raise awareness of ICP among junior doctors and new nursing staff through 30-minute training sessions
- ICP co-ordinator raising awareness about the pathway in different wards and teaching staff to use it
ICP embraced in wards where there has been support by management and senior clinicians and where ICP is seen as a priority (e.g. cardiology wards because staff look after many cardiac patients).

Mechanisms in place for audit and review:
- Staff indicate on ICP documentation whether an activity was met and the reason if not (variances) providing a basis for audit data

- Initial clinical audit compared pathway documentation with traditional nursing and medical records to see whether it captured all the information needed. Checking notes of every patient on pathway to see how it was used and examining the variances
- Too time consuming to check all the notes of patients on MI care pathway
- ICP reviewed annually – Operational lead key role in reviewing process - nursing and medical staff are asked for comments and on the basis of the feedback operational lead re-drafts documentation and circulates for comments
- Review process also incorporates new evidence (e.g. any changes in drug administration etc)
- Ongoing consultation and review of pathway so that it meets users needs and ensure that it is feasible

Table 4.2 continued

Commitment and influence
- Establishment of Pathway Development Team (PDT) comprising senior staff from A&E, General Medicine, Primary Care, Coronary Care and Rehabilitation.
- PDT responsible for overseeing pathway development, providing strategic advice to individual working groups, setting timescales, ensuring that clinical audits take place, identifying training and education requirements. PDT also:
  a) Obtained initial 1-year funding for pathway development and subsequent funding for revising pathway
  b) Attendance to conferences about ICPs
  c) Appointed ICP co-ordinator
  d) Mapping out process of care for cardiac patients and drafting pathway
  e) Designing ICP booklet and guidelines on use
- Setting up of working groups focusing on different aspects of the patient's journey (e.g. acute, rehabilitation and secondary prevention working groups)

Challenges to implementation and sustainability
- Difficulties in raising awareness of MI care pathway especially in the context of high turnover rates among medical and nursing staff
- Implementation seen as an 'on-going process' and importance of leadership and 'championing' the pathway for future sustainability
- Poor compliance: Doctors and staff working on wards where ICP not part of routine practice not completing ICP documentation and/or not familiar with pathway
- More resistance in using pathway because staff not involved in the development process – lack of ownership. Not seen as priority in wards where treatment of MI patients is infrequent
- Training difficult to implement as doctors rotate every few months but less so for nursing staff
- Extending care pathway to primary care:
  o More flexibility required in using the pathway because following discharge more variability regarding patient needs (e.g. age-related needs will differ)
  o Communication between primary and secondary care: where and what information should be passed on

This evaluation revealed some initial concerns that revolved around the ICP documentation and the recording of variances. Specifically, although staff felt that the care pathway was useful as a reminder of the different aspects of care that were required, they were unsure as to how the pathway could be used flexibly for patients that did not 'fit' the anticipated plan of care. The piloting phase also highlighted that greater clarification was needed regarding the use of the variance system. Thus the piloting phase was a crucial aspect of the implementation as it revealed several concerns regarding the early use of the pathway that needed to be addressed through revisions to the documentation as well as staff training and education. It should also be mentioned that a crucial factor to the successful implementation of the care pathway was the accessibility of staff to the ICP co-ordinator and CCU staff (who had been extensively involved in the development of the pathway) who were the first 'port of call' in terms of providing advice and help resolve any problems regarding the use of the pathway.

Within one year of this initial implementation, the acute phase of the MI care pathway was rolled out to all medical wards within the hospital. The pathway has undergone a clinical audit and several revisions which take place on an annual basis. The ICP co-ordinator plays a key part in this process by encouraging staff to provide feedback and comments regarding the usability of the pathway and ways that it can be improved. Ongoing consultation with staff who use the pathway has been a contributing factor to its acceptance as it fosters a sense of ownership as well as ensuring that the pathway is usable and feasible.

4.4 Impact and challenges to implementation and sustainability

This section discusses the key themes that emerged from the informant interviews regarding the ways that the MI care pathway has affected clinical practice and the key challenges identified to the implementation and sustainability of the pathway.

The majority of informants were very positive about the MI care pathway and discussed several benefits for staff. In particular, the pathway was perceived as guidance or 'checklist' to make sure that all aspects of care were delivered and offered a consistent approach to prioritising tasks especially for newly qualified staff. As one staff nurse commented:

> 'As a new staff it is daunting to have to remember everything. The pathway gives guidance, nothing is missed and everyone gets the same treatment. Some nurses have been here for 30 years and they know everything but when you are newly qualified things could be missed or not prioritised in the same order. It's just guidance to make sure that everybody gets the same treatment'.

One informant commented that the care pathway was very helpful for treating cardiac patients because for the majority of cases care can be standardised (assuming that the patient does not present any complications) whilst at the same time not stifling individualised patient care. Thus, the main advantages were the improvement of care by reducing variations and ensuring that nothing was missed, thus making health care staff

more aware of all aspects of care that should be given to cardiac patients. Indeed, strategic reasons behind the Trust's support for standardised care (including care pathways) included the provision of evidence-based care as well as enhancing patient safety by standardising care and minimising risks.

However, not all informants shared this positive view of the care pathway. For instance, one informant commented that the pathway was complicated and did not provide clarity as to what should be done whist others perceived the care pathway as additional workload and 'paperwork'. This issue also emerged at the piloting phase where some nurses expressed some resentment to having to complete their plan of care on the computer as well as completing the ICP documentation. Further, this was a commonly cited reason as to why doctors often failed to complete the care pathway's documentation.

It should also be mentioned that despite the above mentioned benefits, the MI care pathway was not equally embraced across all the hospital wards. Several reasons were given for this variable use. One had to do with a lack of ownership of the pathway as well as lack of 'familiarity' and / or awareness of the ICP and its documentation. Specifically, despite efforts by the Development Group to involve staff from different wards within the hospital in drawing up the paperwork and procedures, staff from general medical wards did not perceive the pathway as 'a priority' because cardiac patients formed only a small group of patients that they cared for.

Informants identified other issues regarding the use and sustainability of the MI care pathway. Specifically, a number of challenges were discussed regarding raising awareness of the care pathway among new nursing and medical staff. Although considerable efforts were made to inform junior doctors and nurses about the care pathway during their induction, this was identified as a key future challenge especially in the context of high staff turnover rates.

Further, nursing and medical staff from general medical wards were often not familiar with the ICP documentation. The interviews suggested that CCU staff appeared to have had more opportunities to attend formal training sessions than staff from other wards. Accessibility to training sessions was easier for CCU staff because they were more involved in the development of the pathway and thus had more opportunities to arrange training sessions. Lack of time was a commonly cited reason as to why staff from other wards had been unable to attend formal teaching sessions.

Finally, some informants commented on the importance of leadership and appointing a care pathway facilitator to ensure that the pathway is '*not forgotten*'. As one informant commented …

> '*I think getting someone to take responsibility for it on a day-to-day basis because if you've not got someone to be thinking about it and pushing it, it would just stop after a period of time.*'

Informants also discussed some patient benefits as a result of the implementation of the care pathway. Several commented that the consistency in the delivery of care had improved because …

> *'you've got that checklist there and the medical staff are working from the same list no matter who they are, what level, what grade they are and the same with nursing staff.'*

This was particularly the case in the CCU and cardiology ward where the MI care pathway had become part of 'routine' and 'standard practice'. It should be mentioned that informants were unable to discuss improved patient outcomes that could be attributed to the care pathway or standardised care alone. However, reduced hospital length of stay was a patient outcome that was perceived to be a result of implementing care pathways. For instance, an informant who occupied a strategic role within the Trust commented on the fact that because care pathways define the expected processes and outcomes of care …

> *'you can deliver the best care that moves the patient through their journey within a reduced time frame and avoid periods when the patient may be stuck into the system.'*

Finally, some informants also commented that patient attitudes towards the MI care pathway were positive. This was because patients and relatives were given a summary of their plan of care and were thus aware of what to expect during their hospital stay. Thus, informants suggested that the pathway had enhanced patient satisfaction through better communication and awareness regarding the patient's plan of care.

4.5 Emerging/key issues

By focusing on a locally developed care pathway, the case study explored the methods adopted in its development and implementation. In doing so, it showed that the methods used have a long-term impact on the degree of acceptance and use of the pathway. Thus, several key factors emerged that if taken into account in the early stages of development and implementation of standardised care can have potential long-term benefits. These are as follows:

- **Involvement of staff to enhance compliance**: As was shown, the pathway was part of routine practice in wards where staff had been involved in the development stages. This was not the case, however, in wards where staff involvement was more variable; this was also reflected in the extent to which the MI care pathway was used. Thus, a key message from this case study is that involvement in the early design stages of care pathways is critical. Involvement may be direct such as membership to a working party or indirect by incorporating staff views in the development and review stages of standardised care

- **Piloting and training as key components of implementation** so that concerns with the use of the pathway are addressed early on and that staff receive the necessary training to be able to use the pathway correctly.

- **Importance of clinical champion/ICP facilitator** at both the development and implementation stages to ensure that staff are consulted and receive the necessary training to use the pathway. This is especially important as in light of clinical commitments, staff may not have the time or be able to organise training sessions. Another key role for ICP facilitators should be to raise awareness of standardised care given that frequent change and / or rotations of medical and nursing staff may contribute to poor compliance.

- **Securing senior clinician and management support** is critical to the successful development and implementation of standardised care. For instance, lack of management support was a commonly cited reason as to why some wards showed poor compliance with the pathway. Further, lack of adequate support from primary care staff (such as General Practitioners) was also a contributing factor for the fact that the MI care pathway has not been extended to primary care. However, it should be mentioned that this may be partly due to fact, as some informants commented, that the needs of cardiac patients following discharge from hospital will be more variable making the implementation of the pathway less feasible in community settings. Nevertheless, this case study clearly illustrates that successful development and implementation of standardised care is incumbent upon management commitment.

Appendix 4e: Midwifery case study : Intrapartum care guidelines

4.1 Organisational context

The midwifery case study took place in a large teaching hospital in the north of England. The Trust was established on 1 April 2001 following the merger of two acute trusts, each with a maternity unit which were re-located onto one site. The Trust became an independent Foundation Trust in 2004. The case study focused on adapting national guidance about intrapartum care, published by NICE in 2007 for use within a maternity service with well-established midwifery-led care guidelines.

The midwifery service comprises more than 250 hospital and community midwives who deal with over 5,000 births every year. Some midwives rotate every few months between the antenatal and labour wards and fetal medicine. The community midwives are attached to GP practices within the city.

4.2 Standardised care with the Trust

Standardised care was reported to be widely used within the Trust. From a strategic perspective, the main function of standardised care was as a management tool, providing explicit, quality standards to ensure safe practice amongst a large, dispersed workforce. A number of models of standardised care were employed within the Trust. These included policies approved by the Trust Board to protect patients and staff. Non-compliance with these, such as the 'do not resuscitate' policy, was described as '*unforgivable*' by a strategic level informant. Other models were protocols, procedures, guidelines, care bundles and care pathways. These were said to be informed by the best available evidence and staff were expected to use them with discretion, according to patient need.

There was a centralised, clinical effectiveness/governance infrastructure and system within the Trust. Clinical governance operated alongside the business processes of commissioning and the clinical effectiveness committee reported to the Trust Board. The system was set up to respond to national guidance and provide evidence of compliance for annual reporting to the Healthcare Commission. For example, in relation to NICE guidance there was a proactive system of encouraging clinicians to become members of the Guideline Development Groups, of tracking progress and commenting of drafts. Audits were co-ordinated centrally to monitor implementation. Clinical governance activities were also devolved to each directorate. There seemed to be less emphasis on locally developed standardised care.

Several strategic and front-line practitioners commented about the extensive use of standardised care within the maternity unit, saying that they had a '*guideline for everything*.' Midwifery-led care guidelines were first launched in 1998. The existing

maternity unit intra partum care guidelines were being reviewed following the publication of the NICE guidance in September 2007.

The maternity unit had well-established systems for guideline development. A Guideline Development Policy outlined how guidelines were to be developed and ratified by the management group. A multidisciplinary Guideline Development Group oversaw the work of three subgroups that developed guidelines for antenatal, intrapartum and postnatal care, respectively. Guidelines were defined as '*systematically developed statements to assist practitioner decisions about appropriate health care*.'

4.3 History of the midwifery-led care guidelines

The midwifery-led care guidelines were instigated by the Head of Midwifery in the late 1990s as way of safely and confidently implementing midwifery-led care based upon evidence-based guidelines. A part-time midwife was appointed on a short-term contract to develop the guidelines. The development process involved a systematic literature review and extensive consultation with midwives and obstetricians. There was a high profile launch with all midwives receiving a personal copy of the guidelines. The guidelines were audited retrospectively, and also before the Trust merger in 2001, when the two maternity units were re-located onto a single site.

After the organisational restructuring, there was said to be little managerial or cultural support for midwifery-led care and so the guidelines '*got lost*.' The revival of interest was attributed to three factors: 1) the government drive to reduce caesarean section rates, to increase the number of normal births and to offer choice about place of birth, including at home; 2) to align with the NICE intrapartum care guideline; and 3) the imperative to comply with Clinical Negligence Scheme for Trusts (CNST) standards and reduce Trust insurance costs.

Following the launch of the NICE intrapartum care guideline in September 2007, the lead consultant obstetrician for guidelines in the maternity unit, asked staff to scrutinise each recommendation and consider their applicability to the local context. The recommendations about normal labour were delegated to a working group of midwives that included the author of the midwifery-led care guidelines.

4.4 Aims and methods of the case study

The midwifery case study provided an opportunity to examine how national guidance is considered, tailored and then introduced into a local setting with well-established clinical guidelines. The original plan was to use a pre-post design to compare the introduction of the clinical guideline on intrapartum care in two specialisms - midwifery-led care and obstetric-led care - and also to investigate any changes in practice, such as the frequency of vaginal examination. However, the delay in the publication of the NICE guideline from February to September 2007, meant that emphasis changed from implementation to development, particularly how NICE guidance is incorporated into the local maternity service.

The case study work was done between July 2007 and March 2008 and comprised interviews and observations. A total of 18 interviews were held with midwives, strategic managers and the operational leads to gain different perspectives on standardised care. Personal or telephone interviews, averaging 60-minute duration, were held with:

- the operational lead for the midwifery-led care guideline

- the operational lead for obstetric guidelines within the Maternity Unit

- five strategic level managers within the Trust and Maternity Unit

- eleven hospital and community midwives as users of standardised care who had a variety of experience, ranging from a newly qualified midwife to midwives who had been working for ten, twenty and thirty years.

Four guideline development group meetings were observed. These were held between December 2007-February 2008 and were attended by three to seven midwives. The meetings lasted an average 85 minutes.

4.5 Development, implementation and sustainability

The key findings about the guidelines as an innovation are presented using an adapted version of Greenhalgh *et al* (2004) unified model. The development, implementation and sustainability results are summarised in table 4.4.

4.6 Impact of standardised care on staff

Standardised care was reported to play a prominent role in the quality and risk management of this large, teaching hospital. The different forms of standardised care had different statuses. For example, a strategic informant said that compliance was expected with formal polices and '*if staff consistently did not observe them, then this could lead to counselling, written warnings and ultimately dismissal*,' whereas guidelines and pathways could be applied with more flexibility as '*only 80% of patients will fit in a particular pathway.*'

Guidelines were described as guidance, a tool, a reference, a reminder that supported safe, evidence-based practice. They were described as '*part of the culture for medical and midwifery staff*' especially as a learning tool for junior doctors to gain experience of common events or complications. Midwives and obstetricians noted the value of practicing drills, mnemonics and guidelines for life threatening situations such as post-partum haemorrhage. However a few informants expressed concern about the growing number of guidelines and the difficulty remembering the revisions to each one. Several people said '*we have guidelines for just about everything*.' Another concern was reliance upon guidelines …

'*when people follow them slavishly, when it is not appropriate. It is a guideline. It is not in tablets of stone.*'

Table 4.3. Key features in the development and implementation of the intrapartum care guidelines

Development

Policy Context:
- NICE intrapartum guideline
- Changing Childbirth, Maternity Matters, Safer Childbirth

Organisational Context:
- Specialised organisation: Large teaching hospital with semi autonomous units and professional knowledge
- Merger of Trusts and maternity units in 2001
- Absorptive capacity for new knowledge: Research active Trust and maternity unit. Trust wide infrastructure for clinical governance, risk management and audit with intranet used for guideline dissemination. Well established infrastructure in maternity unit for developing, auditing and up-dating clinical guidelines.
- Receptive context for change: strategic support with guideline development led by consultant obstetrician; some midwives given dedicated time to participate in the guideline development group. Resources allocated to meet some NICE recommendations (eg. baths for pain relief in labour).

Features of standardised care:
- Relative advantage: evidence from NICE, outcomes research and qualitative experiences of women to support midwifery-led care for low risk births at home or in hospital
- Compatibility: with professional values about normal birth, promoting informed choice and supporting women
- Complexity: builds upon established midwifery-led guidelines and other protocols, guidelines and policies used within the Trust.
- Trialibility: audit of recommendations planned concurrently with guideline development, for example about one-to-one care
- Observability: benefits of NICE supporting some aspects of midwifery-led care and normal birth.
- Task relevance and usefulness: midwifery-led care relevant in hospital and for home births; guidelines provide agreed care standards and used as a reference or guidance, with discretion. Also, a reminder with some sections more detailed for inexperienced midwives working on their own.

Implementation and Sustainability

Adoption:
- Psychological antecedents: instigated by midwives passionate about normal birth.
- Meaning: instilling confidence by providing the evidence for natural processes and interventions, and thus midwifery-led care.
- Nature of adoption decision: combination of authoritative and collegiate decisions with the completed guidelines endorsed by the maternity directorate.

Adoption and early use:
- Updating and aligning locally developed guidelines with national guidance: most of the NICE recommendations were seen as supportive, for example, recommendations about second stage of labour were described as '*that is great for us*.'

Communication and Influence:
- Influence: expert, peer opinion leader devised and now updating the midwifery-led guidelines with a group of experienced midwives.
- Boundary spanner: instigator with relationships across hospital/community boundaries and with the RCM (professional body).

Challenges to Implementation and Sustainability:
- Several informants noted the proliferation of guidelines, saying that there was one for everything. The collated guidelines were described as an '*inch thick textbook*.'
- Concerns expressed about alerting a large workforce to the changes and then ensuring that staff used the latest version. Dissemination plans included using email and a regular newsletter to remind staff. Current versions accessible via the hospital intranet which was difficult for community staff to access.
- Mechanisms for audit and review shows organisational capacity to monitor, evaluate and update the guidelines.
- Staff involvement: credible peers (midwifery managers and practitioners) as members of the working group updating the guidelines.

Table 4.3 continued

- Feasibility: guideline development group discussed practical implications of the recommendations in a busy labour ward (eg. obstetrician's preferred drug regimes) and in the community (eg. travelling times).

Development Process:
- Key priorities for implementation of the NICE guideline identified at special meeting and lead obstetrician delegated normal labour guidelines to a working group of midwives.
- Midwifery-led care guidelines updated by a small group of midwives. Informal, egalitarian meetings without agenda or minutes. Tasks shared with members appraising primary research, consulting other guidelines (for example about water births) and preparing audit tools for discussion at the meetings.
- Facilitation: updated guidelines to be promoted at a study day about home births.
- Commitment and influence: strategic commitment to standards that reflect 'best practice,' to manage risks and to maintain the reputation of a large organisation with a dispersed workforce.

- The midwifery guidelines were reported to be accepted as routine practice with any variation attributed to women's choice, resources (staff shortages) and concerns about the health of the mother or the baby when the mother would be transferred to obstetric-led care.

Midwives described themselves as autonomous, independent practitioners who worked in close partnership with woman, giving information and facilitating informed choice, so it was the woman's decision, with one saying …

> 'it's great to see women empowered and knowing that you've been involved in that empowerment.'

Midwives and obstetricians gave examples of midwives challenging medical staff when they were not complying with a guideline. One midwife gave an example, saying …

> 'the guideline gives you authority to question a decision … the guideline is there for best practice … and I was aware of the guideline and that he shouldn't be making that decision.'

4.7 Impact of standardised care on women

There were different perceptions about whether women knew that they were being treated in accordance with some form of standardised care. For example, women were reported to be unaware of NICE guidance, not mentioning it during consultations and it was also not referenced in the locally developed woman-held record. Whereas an obstetrician described a '*personalised protocol*' that contained tailored instructions for

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each women with diabetes. Some midwives reported interpreting guidelines for women, their partners and families. One experienced midwife observed …

> 'If you did feel that you had to do something that the guidelines said, then you would talk to the woman about that … it was me interpreting them and saying why they were there.'

A strategic manager emphasised the value of standardised care for women with complex medical, social and psychological problems such as diabetes, asylum seekers and substance misuse. This was because the standardised care allowed midwives to *'look at the whole woman and not stigmatise women'* because everyone was asked the same questions.

4.8 Impact of standardised care on the organisation

The involvement of knowledgeable, enthusiastic practitioners, who would speak from experience, was seen as important for credibility, ownership and ultimately for acceptance and use of the guidelines. There were some negative comments about the *'industry'* associated with standardised care. It was described as *'a big beast.'* Development and audit were portrayed as time-consuming. The duration was said to vary from three-four months to develop uncontroversial ones, through a *'year or two'* for the NICE intrapartum guideline because of the number of recommendations to be considered, and up to two years for evolving subjects, such as clinical obesity, where there were not any national guidelines.

During the midwifery-led care guideline development group meetings, the key priorities recommended by NICE for normal labour were scrutinised section by section, with points accepted, discussed, or changed or removed. Some recommendations were described as 'great' when they supported normal birth and the existing midwifery-led care guidelines. There was much debate about the research underpinning the recommendations. For example, the primary studies were obtained to help interpret the recommendations as these were not graded by NICE according to the strength of the evidence. On a few occasions, the group disagreed with the recommendations, either because they interpreted the research differently or because they did not think that they were feasible to implement in practice. In some instances, the decision was deferred as further discussion with, or endorsement by, the obstetricians was needed.

The importance of resources, particularly time, staff and equipment, were highlighted by many informants. For example, the NICE recommendation about one-to-one care was reported to be *'just not feasible, we don't have enough resources'* and the recommendation about using water baths for pain relief would take time to implement because of the cost implications of new facilities.

4.9 Emerging issues/key points

The case study highlighted a number of broader, cross-cutting issues:

- The possibility of a local innovation developing in a similar way now is called into question by the Trust's strategic emphasis upon meeting national targets for the Healthcare Commission.

- Hidden cost of the time and infrastructure associated with development, ratification, audit and review, which does not seem to be less when national guidelines are adapted to local circumstances.

- Standardised care as a way of de-stigmatising some issues as all women are asked the same question, a point reiterated in the health visiting case studies.

- More emphasis upon dissemination with less emphasis upon training to use standardised care than in other case study sites. This seemed to be for two main reasons: the changes in practice were minor and so training was not required and staff were expected to keep up-to-date to adhere to their code of professional conduct.

The key points about this case study:

- An existing midwifery-led, locally developed guideline that contained the evidence for midwifery-led care and supported midwives to be confident in offering natural child birth and choice for low risk women. The guideline marked a way of introducing midwifery-led, with a high profile launch and the first day marking a change of practice. Development instigated by the Head of Midwifery in the late 1990s. The guideline had been audited and updated.

- The revision was part of a larger review to align the current maternity unit guidelines with the 2007 NICE clinical guideline for intrapartum care. Few changes needed as the midwifery-led care guidelines that informed midwifery practice for hospital and home births, were similar to the NICE guideline.

- Organisational change: during the last decade, two Trusts merged into one, and the two maternity units were relocated onto a single site, making a large unit, with new managers and a culture of higher risk, obstetric-led care.

- The importance of woman making informed choices, with midwives acting as advocates and brokers, interpreting the guidelines. A midwife commented …

    'I think guidelines are fine as long as they are not used in an authoritarian way, and this idea of informed choice is still very much at the forefront.'

- A setting where there 'was a guideline for just about everything' and where 'our mistakes are life threatening … and that's why we've got protocols and guidelines' (midwife) with compliance expected when giving obstetric-led care.

Appendix 4f: Health visitors case study 1. Care pathway for maternal depression

4.1 Organisational context

This is the first of two health visitor case studies. This case study was situated in a Primary Care Trust (PCT) in the south of England. The PCT was established on 1 April 2001. It serves an urban area, which includes some areas of high deprivation and combines commissioning and provider roles. The case study investigated a well-established, locally developed integrated care pathway for maternal depression that has gone through the development, implementation, audit and review stages. The health visitor service has undergone considerable change over the last few years with the move from a Children's Services Directorate to Child and Family Teams. Each team, which comprises health visitors, school nurses and nursery nurses, is based in a geographical area rather than being attached to GP surgeries. This enables the service to focus on public health, population-based work as well as providing a universal and targeted service for vulnerable families.

The Trust employs less than 50 health visitors. Most are employed on Agenda for Change, Band 6 as this reflects the skills required to detect vulnerabilities and to provide a needs-led service. Each health visitor sees about twelve new births a month. Women with post natal depression receive an enhanced service.

4.2 Standardised care within the PCT

The care pathway for maternal depression is the only care pathway used by health visitors. The care pathway was intended to mainstream working with women with post-natal depression. This meant making the detection and management of maternal depression 'core business' for all health visitors.

There is also a set of protocols, which provide guidance, as checklists for common procedures. The set of protocols are issued to new staff at induction.

4.3 History of the care pathway

The care pathway was instigated by health visitors who were passionate about health promotion and were familiar with research that showed the importance of child-mother bonding for future well-being. The development started in the late 1990s and was undertaken by a multi-disciplinary working party, chaired by a health visitor. This stage took 18-24 months.

Implementation was preceded by training for all staff by an external expert, which included a programme to prepare some staff to be trainers. There was a period when the pathway was described as being in abeyance. This was for several reasons: the

pathway was perceived as optional; it was at a time of staff shortages and the pathway was '*leaderless*' following the re-deployment of the health visitor who started the pathway. The pathway was re-launched in 2005 when the operational lead returned in a management post. A strategy to promote the identification and primary management of maternal depression in the ante and postnatal period was produced and endorsed by the Professional Executive Committee of the PCT. The strategy aimed to embed the pathway into routine practice as core business for health visitors.

An audit of the postnatal care pathway was done in 2006 by checking compliance across 100 randomly selected sets of notes. The audit revealed that the pathway was not being completed but that the information (about the detection and management of post natal depression) was recorded in the women's notes. The care pathway comprises a flow chart and two, two-page records of care for the antenatal and postnatal period respectively.

In 2007, a working group, led by a health visitor was established to review the care pathway. The intent is to improve the format, taking into consideration the audit results, and also to amend the content to reflect the guidelines about maternal mental health published by NICE in 2007.

4.4 Aims and methods of the case study

The case study work involved investigating the impact of using a locally-owned and developed innovation – an integrated care pathway - that had been endorsed as pivotal to the professional role of health visitors. The care pathway had completed the cycle of development, implementation and audit. We were interested in whether the pathway had affected the knowledge, confidence and action/s of health visitors.

Two researchers spent three days at the case study site in December 2007 doing interviews and a focus group to explore different perspectives on the care pathway.

Seven health visitors from one team participated in a focus group and interviews were held with five people. The interviewees were:

- the operational lead responsible for developing the pathway

- two team managers/health visitors who also use the pathway

- a strategic manager

- a health visitor who had instigated early work about post-natal depression.

Interestingly, two strategic managers declined to be interviewed: one for work pressure reasons and another because they did not consider standardised care to be relevant to their commissioning role.

The individual interviews and the focus group were appraised separately before being combined in this report. The integration was to triangulate the data and also to enhance

the richness of findings (Lambert & Loiselle 2008), which are of course limited to this particular setting and pathway.

4.5 Development, implementation and sustainability

The key findings about the integrated care pathway as an innovation are presented using an adapted version of Greenhalgh *et al* (2004) unified model about the adoption and spread of innovations. The development, implementation and sustainability results are given in table 4.5.

4.6 Impact of standardised care on staff

A small number of health visitors took a lead role in overseeing the development and then sustaining the pathway. There was unanimity about the importance of detecting post natal depression and the health visitor interventions. The pathway is now embedded in routine practice as evidenced by the participants' descriptions of the training, examples of using the pathway with women and discussing the pathway in supervision sessions.

The pathway was described as a tool, a prompt, an evidence-based guide supporting safe practice that assisted, but did not replace their professional judgement. It was said to give confidence, to be empowering as the health visitors knew that they were '*doing the right thing*.' The pathway made it legitimate to raise potentially sensitive topics, like anxiety, depression and partner abuse, with every woman in a routine, normal way. It also provides a structure for thinking and acting: for starting and stopping listening visits and for referring to specialist mental health services.

However, it was difficult to detect what exactly was used. For example, was it the documentation – the flowchart and the pathway? Or, was it the specialist knowledge, skills and confidence gained through the training?   Or, had the pathway become internalised, as part of their professional repertoire, through familiarity, use and supervision?   The audit results suggest that the pathway was not used, but this was only because the separate form had not been completed and further investigation showed that the activities were documented, but in the health visitor record.

There were some divergent opinions about whether the pathway is and/or should be strictly complied with. Three main reasons were offered:

1. A manager identified resource reasons especially staff shortages that may preclude the second screening visit; or require it to be done in a different way, for example at a clinic rather than at a home visit; or to be targeted at higher risk women only.

2. There was some debate about whether the pathway should be used in isolation, as the sole purpose for a home visit rather than combined with other activities, which better reflects their holistic approach to families.

3. These was some disagreement about whether the clinic was an appropriate place to ask questions about mood.

The only criticism related to the usability of the form. It was described as cluttered with small font. Some health visitors said they preferred a checklist, to act as a prompt, rather than a separate, additional record of care which was an additional administrative burden.

Table 4.4. Key features in the development and implementation of maternal depression pathway

Development	Implementation and Sustainability
Policy Context: ▪ National Service Framework for Mental Health ▪ SureStart programme – funding and raised profile of post natal depression (PND) **Organisational Context:** ▪ Specialised organisation: Primary Care Trust (PCT) with semi autonomous units and professional knowledge ▪ Previous PCT - organisational restructuring in the late 1990s when the pathway was being developed ▪ Knowledge: showed capacity to use existing knowledge as single PND support group run by a health visitor/ex community psychiatric nurse; and also to absorb new knowledge – 40 page resource with evidence underpinning the ICP was complied during development ▪ System readiness for change: tension for change with sole PND group and staff motivated to use best evidence and change the service within the Trust **Features of standardised care:** ▪ Relative advantage: evidence about effectiveness of screening tools and interventions (eg listening visits) ▪ Compatibility: with professional values and needs for an equitable service across the PCT ▪ Complexity: new documentation, formalising number and purpose of visits with prescribed activities ▪ Trialibility: pathway 'experimented with' after training when it was seen as optional	**Adoption:** ▪ Psychological antecedents: instigators motivated to innovate, to improve services ▪ Meaning: associated with evidence-based care and a universal service de-stigmatising maternal mental health ▪ Nature of adoption decision: collegiate health visitor (HV) and then authoritative decision with endorsement by PCT and inclusion in service level agreements **Adoption and early use** ▪ Awareness: through training for all health visitors ▪ Concerns during early use: perceived as optional so not used consistently ▪ Formal re-launch – health visitors expected to use the ICP from this date **Communication and Influence:** ▪ Influence: health visitor champion who has driven the ICP from start (except for period when not in post) ▪ Boundary spanner: instigator with relationships across levels of the PCT, with the CPHVA (professional body) and invited to share experience with other organisations **Challenges to Implementation and Sustainability** ▪ Some dedicated time/resources, for staff training and team leaders with staff development role ▪ Mechanisms for audit and review shows organisational capacity to monitor, evaluate and update the ICP ▪ Staff involvement: credible peers leading the development and audit; and all involved through training with some staff as trainers

Table 4.4 continued

- Observability: benefits of evidence-based practice with more support groups clearly visible
- Task relevance and usefulness: detection and treatment of PND 'core business' for health visitors with pathway supporting performance by providing specialist guidance, as an adjunct to professional judgement
- Feasibility: new and extra documentation (the ICP form) to be completed

- The pathway reported to be accepted as routine practice with some variation attributed to resource reasons (staff shortages) and needs of the women
- Making the ICP documentation 'user friendly' to make sure it is completed and agreeing who should hold the information (women and/or health visitors)

Development Process:
- Instigated by health visitors familiar with research about bonding and vision about health promotion role
- Multi-disciplinary, inter-agency group chaired by a health visitor
- Facilitation: funding for external expert to provide a 4-day training programme to equip health visitors with the knowledge and skills to assess and provide listening visits; and also to 'train trainers' to offer annual training for new joiners
- Commitment and influence: strategic document about the ICP endorsed by the Professional Executive Committee of the PCT

There was also a debate about who should hold the record (the health visitor or the woman) and where it should be kept (by the woman or in the health visitor records). A secondary concern was about whether the screening tools were appropriate for women from different cultural/ethnic groups.

The health visitors who had been involved for almost a decade expressed disappointment and despondency about the pathway. For example, one questioned whether it was '*a dead duck as a pathway*' because the audit had failed to give evidence about the effectiveness of the health visitor service, because the form had not been completed. Another was concerned about changes driven by resource rather than research reasons, for example, when the second screening visit was abandoned due to staff shortages.

4.7 Impact of standardised care on women and their families

Three positive impacts of the pathway were reported. These were 1) the stigma associated with mental health problems were reduced because all mothers were asked about their mood; 2) gaps in services had been identified and filled, for example by

Queen's Printer and Controller of HMSO 2007 *Queen's Printer and Controller of HMSO 2007*
increasing the number of support groups for mothers; and 3) there was also anecdotal evidence about fewer behavioural or sleep disorders in children. These were said to result from the improved support for mothers and better maternal-child bonding. However, there had also been a large increase in the percentage of women identified as vulnerable with 15-30% expected, but 50-60% being detected. This was also being explored by the review group.

4.8 Emerging issues/key points

The case study highlighted a number of broader, cross-cutting issues:

- The possibility of a local innovation developing in a similar way now, or in the future, is called into question by the new business processes and the strategic emphasis in the PCT on accountability and benchmarking against national standards and meeting national targets for the Healthcare Commission.

- All three health visitor case studies noted the problems of involving midwives in the antenatal stage of care pathways about maternal mental health. Similar reasons were given on each site. These were a) midwives and health visitors employed by, and accountable to different organisations which hindered seamless services to women; b) midwives had difficulty access funding for and/or being released to attend training sessions due to work pressures and staff shortages; c) concern that 10-minute consultations did not give sufficient time to explore mental health concerns; and d) that midwives were not trained to deal with women who are anxious or depressed.

- The debate about whether health visitors or women should hold their records, suggests a change in attitude over the years from professional held documentation to patient held records.

The key points about this case study:

- A health visitor-led, developed and delivered local innovation which involved introducing an integrated care pathway to detect and manage maternal mental health problems. Development started in the late 1990s and the pathway has been through the processes of introduction, use, re-launch, audit and is currently being reviewed to align with NICE guidelines and incorporate the feedback from the audit.

- During this period, the PCT and the health visitor service have gone through considerable professional and organisational changes with service reviews and reconfigurations; moving from GP attachment to corporate case loads and from a traditional surveillance role to a public health promotion/prevention role.

- The pathway, with the associated training programme, has made the specialism of post natal depression, core and routine practice for health visitors.

Appendix 4g: Health visiting case study 2. Maternal mental health protocol

4.1 Organisational context

This is the second of two health visitor case studies. This case study was based in a Primary Care Trust (PCT) in the west of England. The PCT was established in October 2006 from the merger of smaller, separate Trusts. The new PCT serves a multicultural community living in urban and rural areas; and combines provider and commissioning functions.

The case study focused on a well-established, locally developed protocol for maternal mental health. The protocol has gone through the development, implementation and audit stages in the founding Trust. The protocol is undergoing review as part of harmonising operational policies across the new trust. The revision is also taking into consideration the recommendations contained in the NICE clinical guideline about maternal mental health (NICE 2007).

The health visitor service is in transition and undergoing a major review and modernisation following the merger of the trusts into one. The new trust employs over 100 Whole Time Equivalence (WTE) health visitors which means approximately 150 staff due to part-time working. Most health visitors are based in General Practice surgeries. Community staff are members of, and supported by a Practice Development Unit (PDU) that is accredited by a nearby University.

There are over 5,000 live births per annum with a 13% incidence of post natal depression, which reflects the national average. The maternal mental health protocol is used, formally or informally, on each contact with women during the peri-natal period (ante-natally and during the first year after birth) at approximately 6,000 contacts per annum.

4.2 Standardised care within the PCT

The protocol for maternal mental health is one of the main forms of standardised care used by health visitors. The original aims were to '*provide women with the opportunity to have their mental health needs identified and assessed and be offered effective support, advice and treatment*' (2006, p4). As such, the protocol is considered to be core to the work of health visitors, both in the original and new PCT.

4.3 History of the protocol

The maternal mental health protocol has gone through several iterations since it was started in the late 1990s. It was instigated and led by a core group of health visitors with a special interest in mental health. The need for a protocol emerged as a result of a benchmarking questionnaire that showed variation in the identification of maternal depression and an absence of a common approach to treatment. The protocol was

originally launched in 2000. It was evaluated in 2003 and revised by a multi-disciplinary group chaired by a health visitor. Following an 18-month development period, a new evidence-based protocol, endorsed by the PCT was launched in March 2006. The protocol was audited in the founding PCT in 2006 with the support of the Audit Department.

The protocol is currently being revised by a multi-disciplinary steering group, chaired by a health visitor. Members include a midwifery matron, the lead primary care mental health worker and health visitors from each of the former PCTs. Working groups are established for specific tasks, such as planning the training needs analysis.

4.4 Aims and methods of the case study

The second health visitor case study focused on the maternal mental health protocol as a locally owned innovation that is endorsed as pivotal to the professional role of health visitors. The aim was to explore the use and the success factors, particularly why the protocol has been sustained in routine practice at a time of organisational change.

The case study work was done in January-February 2008 and two researchers spent three days on site. A range of methods were used to gain a multi-perspective on the protocol. The methods included an observation, a focus group, interviews and documentary analysis. A focus group was held with four health visitors, the minutes of protocol steering group meetings were scrutinised and a two hour meeting was observed. A total of 12 interviews were held with:

- the operational lead responsible for developing the protocol

- two team/operational managers who were both health visitors

- a strategic manager

- three multi-disciplinary members of the steering group

- five health visitors as end-users of the protocol.

The individual interviews and the focus group were appraised separately before being combined in this report. The integration was to triangulate the data and also to enhance the richness of findings (Lambert & Loiselle 2008), which are specific to this site and time.

4.5 Development, implementation and sustainability

The key findings about the development and implementation of the protocol are presented in Table 4.6 using an adapted version of Greenhalgh *et al* (2004) unified model for the adoption and spread of innovations. The development, implementation and sustainability results are set out in Table 4.6.

Table 4.5. Key features in the development and implementation of the maternal mental health protocol

Development	Implementation and sustainability
Policy context: o NSF for young children and younger people o NSF for mental health o NICE Guidelines for antenatal and post natal depression	***Adoption:*** *Nature of adoption decision:* o Collective decision: multi-disciplinary, bottom-up instigation in response to need with top-down support
Organisational context: o Practice variations in the identification of maternal depression and delayed referrals to mental health services o Need for early detection of depression and to establish clear pathway as to where and when referrals should take place o Need for a common approach to the detection and management of depression, especially for health visitors without a background in mental health **Features of standardised care:** *Relative advantage:* o Earlier detection of depression and clear path for referral process o Same standards of care provided to all women by providing a unified approach to detection and treatment o Provides structure, clarity and a strong evidence base o Improved communication between the primary care team and the mental health team, and between HVs and GPs o Spin-off services for women such as support groups o Protocol flexible which is important because treatment of depression is not '*clear-cut*' *Compatibility:* o Compatible with the professional values and learning needs of staff o Maternal mental health high on the staff agenda and protocol is integral to the work of health visitors in the founding trust **Development process:** *Initiation* o Original protocol instigated in late 1990s three health visitors and a child protection nurse o Development group established in 2006 to 'revamp' protocol for the new, merged trust	**Adoption and early use:** *Launch:* o First protocol launched in 2000 in founding trust o Training for health visitor and midwifery team leaders and cascaded to all staff in founding trust o Employed external trainer with special interest in maternal depression and also 'trained own trainers' so able to run training 'in-house' o Revised protocol launched in March 2006 with a half day event attended by midwives, health visitors, nursery nurses. Event provided opportunities to ask questions and delegates received a copy of the protocol o Also three launch awareness sessions for health visitors, midwives, mental health workers and everyone involved in the delivery of the protocol *Early concerns:* o It is a greater, more complex task to systematise practice in a community setting in a larger geographical area with a dispersed workforce o History of formal and informal post natal depression protocols in other trusts, in addition to the founding trust, which is leading the harmonisation in the new organisation **Communication and influence:** o Multidisciplinary steering group meeting to revise protocol in readiness for adoption across the new trust o Good communication between management, mental health colleagues and other stakeholders, including some user involvement o Some parts of protocol adopted by a neighbouring trust following a maternal death

Development	Implementation and sustainability
Table 4.5 continued *Facilitation* o Multidisciplinary steering group consisting of health visitors, midwives, voluntary agencies, psychiatric staff, and led by the health visitor/professional development manager o Steering group reviewed research and policy to guide development of a step-by-step protocol o Indirect involvement of relevant workforce through regular meetings and forums has facilitated ownership and adoption of protocol o Gained approval from clinical governance sub-committee at directorate level o Training needs identified and implementation plan produced *Commitment and influence:* o Obtained support/ '*sign up*' from senior management team for the protocol o Chair gained approval for protocol from nursing clinical governance committee and PCT sub-committee o Merger has led to a commitment to use the updated protocol across the new trust. o National and local drivers encourage practice and raising awareness about post-natal depression o Both bottom-up and top-down support for protocol as a quality standard for the trust	**Mechanisms in place for audit and review:** o Retrospective baseline audit with health visitors reporting their practice the previous year, in relation to the original protocol o Audit repeated a year later to determine the impact the revised protocol had on practice. Included a questionnaire and review of randomly selected set of clients' notes. Results analysed by the audit department with the results showing that the protocol had influenced practice. Earlier and increased rate of detection of depression o Protocol currently being updated in accordance with NICE maternal mental guidelines published in 2007 **Challenges to implementation and sustainability:** o Challenge of keeping the protocol a priority development in the context of organisational restructuring, service review and reconfiguration. o Additional 3-4 month formal assessment of women adds to an already high workload, exacerbated by decreased staffing levels following merger o Effort and commitment to review protocol, use and audit across new, larger organisation with new stakeholders and in other localities with less/different mental health support services for 'at risk' women o Variation in socio-economic and ethnic minority groups means some women may have difficulty accessing services that are available to them

4.6 Impact of standardised care on staff

The protocol is well regarded in the founding trust, being described as '*a tool*' and a '*guide*' that provided a '*safety net*' and confidence from being '*evidence-based*' about a specialist topic – mental health. The benefits of knowing that the health visitors were providing a quality, consistent service to all women was emphasized, as was the ability to use the protocol flexibly, to exercise judgement and tailor to the needs of individual women. As such, it was compatible with health visitors' professional values about equity and a universal service. The protocol is embedded in the core programme for health visitors which means that maternal mental health is seen as a priority and *'core business'* allowing staff to spend time on this work, at a time of organisational change and uncertainty.

Other benefits reported were the practitioner-led, bottom-up development process that meant that the protocol was '*credible*' and '*workable.*' There was a sense of ownership from both direct involvement as a member of the development groups, and indirectly amongst the wider workforce, who had been kept informed of progress and their views sought, at regular meetings. Membership of the strategic development group and working groups was described as '*fluid'* with new staff with particular skills and expertise being involved at different stages, including a health visitor student who had worked as community psychiatric nurse. The continuity of leadership also seemed important for maintaining the profile and momentum of the protocol when the trusts were merged.

The protocol also '*legitimised*' and '*normalised'* maternal mental health problems, allowing health visitors to allocate resources to this speciality and collaborate with primary care mental health workers. The shared training gave opportunities to share and learn from each other and was reported to enhance networking, providing a '*more joined up'* service to women and their families. There was a sense that the protocol provided clarity, a supportive structure and safeguarded practice. This in turn seemed to enhance confidence and competence when delivering care because the protocol provides a clear framework in which to work, despite so many other demands on their time.

One stated advantage of the protocol was that it was not overly prescriptive, it provided clarity regarding the mood assessment and interventions such as the listening visits, whilst allowing for clinical judgement. This flexibility in its application was perceived as important for some health visitors for two reasons: 1) because the treatment of depression is not *'clear cut'* and not every client will fit the protocol, and 2) the protocol is *'open'* thus allowing for deviations and professional judgment. As one health visitor commented:

> '*It's not too prescriptive which is a plus. Protocols can give too much detail about every little thing that has to happen… Many health problems can be much more varied and less clear cut about what is the right intervention. The protocol is open enough to allow for this. It is about consultation with the worker or mental health team at this point. The pathways are detailed enough so staff know what to do, at what stage but still open; it is not cook book medicine.'*

On the whole, health visitors perceived the protocol as setting a standard of care but at the same time not restricting professional autonomy and decision making. The protocol was a guide, a reference document rather than additional documentation to complete.

4.7 Impact of standardised care on women and their families

The protocol was seen as supporting more uniformity of care, so women receive a more consistent service and can also form realistic expectations of the quality of care that should be delivered. Multi-disciplinary working also positively impacts on women, through improved communication between the primary care team, the mental health team and between health visitors and general practitioners.

A major impact of the protocol for women is the spin off services that have developed, particularly the support groups for mothers with mild to moderate depression which were jointly run by health visitors and graduate/primary care mental health workers. The

support groups had been positively evaluated by mothers in the founding trust. However, there was concern whether there would be sufficient resources to offer similar support groups across the new trust.

4.8 Key issues

- A health visitor-led, developed and delivered local innovation which involved introducing a protocol to identify and treat women with mild to moderate depression. Development started in the late 1990s and the protocol has been through the processes of introduction, use, re-launch, audit and is currently being reviewed to align with NICE guidelines and to roll-out across the new, larger PCT.

- During this period, the PCT has been restructured, with Trusts merging into one. The health visitor service is also going through considerable professional and organisational changes with service reviews and reconfigurations.

- The protocol, with the associated training programme, has made the specialism of post natal depression, core and routine practice for health visitors.

- Success factors included continuity of leadership and strategic support for the protocol at a time of organisational change; the widespread sense of ownership from health visitors only indirectly involved in the development – through communication and consultation; the enduring interest/passion of some staff in mental health and the importance of bonding for longer term health outcomes; and '*normalising*' mental health problems through inclusion in the universal health visiting service.

Appendix 5a: Economic literature review

5.1 Introduction

When considering the use of standardised care, as with any health care intervention, due consideration needs to be given to its cost-effectiveness. In order for this assessment to be undertaken the costs and effects of the standardised care 'package' need to be compared to the situation where no standardised care is available. It is also important that the full range of costs and effects associated with the package are evaluated. Grimshaw and colleagues (Grimshaw et al. iii-iiv) highlight the need to consider three distinct stages than must be considered in any economic evaluation; development, dissemination/implementation and the treatments effects/costs related to behaviour change. Yet in their review, of all 'rigorous' evaluations of guidelines prior to 1999, of the 235 evaluations identified, only 63 (26.8%) reported either any cost analyses, and only 4 (1.7%) reported the costs of development and dissemination/implementation.

This literature review had two aims. Firstly, to assess how standardised care has been evaluated within cost-effectiveness analyses, and secondly, to assess the costs of development and implementation. These two issues are described in separate sections below, followed by conclusions relating to both issues.

For the purposes of this review 'development' refers to the resources needed in order to devise the standardised care package, for example staff time for meetings, and literature reviews. 'Implementation' refers to the resources needed for staff to operationalise the standardised care but excluding treatment costs, for example, educational or training programmes relating to the protocol. Included within this are the costs of monitoring, for example, audit and data analysis. 'Consequences' refers to the costs of providing care, and any impact it may have on subsequent contacts with the health service.

It is recognised that different interpretations/definitions are possible, for example, Lighter and Fair include education, service costs and data analysis within 'implementation' (Lighter and Fair). Within the terminology used here, whilst education and data analysis are integral to the implementation of standardised care, the provision of the service itself would be deemed a consequence of the care pathway. These differences should not detract from the findings of this review, however, care must be taken when the results are compared to other papers as they may use different definitions.

5.1.1 Economic evaluations of standardised care

In common with the other literature reviews in the study, several search strategies were examined in order to assess the number of hits and the likely yield of useful studies. Broad searches using general terms such as 'guidelines' and 'cost', which were repeated across several databases, produced thousands of hits with the vast majority having no

relevance to our stated aim. This is a product of these terms being used frequently within articles as part of the general narrative, even when central issue of the paper is something quite different.

As a consequence of this, a more specific search strategy way developed using the NHS Economic Evaluation Database (NHS EED). NHS EED includes published economic evaluations that have been systematically identified through electronic searches of MEDLINE, CINAHL, EMBASE and PsycINFO, together with hand searching of a wide range of journals and grey literature sources. Following the identification of possible studies, considerable effort goes into filtering the results to exclude irrelevant studies so that the database just contains economic evaluations. However, NHS EED is still affected by the problem of common usage of the terms 'guidelines', 'protocols', etc. Consequently, to narrow this down searches were conducted for economic evaluations with either 'guideline' or 'protocol' in the title to ensure that these forms of standardised care were central to the evaluation. These searches identified 42 articles, all of which were retrieved. One was subsequently excluded from the review as costs were not valued in monetary units (Konski et al. 575-78) and another as it was in a foreign language (Del Cura et al. 478-89).

The papers were reviewed by a single researcher (SD) and data were abstracted on the context of the evaluation (e.g. country, condition, aspect of care), the presence of cost information on the development, implementation and consequences of standardised care implementation, and the conclusions relating to costs. The description of conclusions was kept to a minimum as the focus was the degree to which protocol development and implementation costs were included.

5.1.2 Results

Data from 40 papers were abstracted and are summarised in Table 23. All but four studies (Tilley et al. 143-49;Robling et al. 402-07;Schmidt et al. 63-69;Hoeijenbos et al. 85-98) focused purely on the consequences of the standardised care. The studies that looked just at consequences typically looked at total costs, but in many circumstances just focused on the single aspect of care that was the focus of the protocol or guideline. For example, when examining the use of continuous neuromuscular blockade in critical care patients, MacLaren and colleagues looked at only the acquisition costs of drugs (MacLaren et al. 49-55).

Whilst Robling and colleagues did estimate the costs of seminars and feedback, these were not described in any great detail (Robling et al. 402-07). Resource use was not described and so we are uncertain as to what items are included in their estimated costs. In contrast to the majority of other studies in Table 5.1, Robling did not include the total costs of care that were a consequence of the protocol; their costs refer just to telephone access to imaging, and not to the cost of the imaging and related care. Additionally, Robling did not include the costs of developing the guidelines in their estimates. In contrast,

Tilley and colleagues did include the costs of guideline development within their costs, however, these can not be disentangled from the total costs used in their analysis (Tilley et al. 143-49).

The studies by Hoejinbos (2005) and Schmidt (2002) gave more detailed breakdowns of costs relating to implementation, however, these were derived in quite different ways. Hoejinbos gathered detailed information on items of resource use and produced a cost of implementation through this 'empirical' approach. In contrast, Schmidt generated their costs through professional opinion of what 'would be needed'.

It should be noted that several studies implicitly identified resource use relating to development and implementation, but these were not included in the economic evaluation. For example, Jones and colleagues noted that continued efforts at staff education and reminders in newsletters were used during protocol implementation (Jones et al. 926-30). The lack of inclusion of these costs in studies appears to be due to the financial focus of the studies, with the American studies in particular focussing on charges or budgets. Consequently, costs predominantly relate to those where there are direct financial consequences associated with it.

5.1.3 Discussion

No studies looked at all three stages of standardised care considered necessary for a comprehensive economic evaluation (Grimshaw et al. iii-iiv), i.e. development, implementation/dissemination and treatment consequences. Only four of the studies identified in this search examined costs other than the treatment consequences of the standardised care (Robling et al. 402-07;Tilley et al. 143-49;Schmidt et al. 63-69;Hoeijenbos et al. 85-98). This clearly demonstrates a lack of appreciation for the opportunity cost of staff time required in the development and implementation of standardised care.

Whilst it is clear that protocol development and implementation costs are rarely included in economic evaluations, we must consider whether this is reasonable omission. Grimshaw and colleagues (2004) consider when it may be legitimate not to include all components of cost within an economic evaluation of guidelines. They argue that it may be justifiable to exclude the costs of development and implementation if they are considered to be so small that 'they could not possibly cancel out any savings in treatment costs' (Grimshaw *et al,* 2004 p43). However, they also recognised that the justification for omitting these costs should be explicit and supported by appropriate evidence.

For one study, the omission of development costs is probably reasonable and so their inclusion of just implementation costs is legitimate. Hoeijenbos (2005) looked at the implementation of pre-existing national guidelines among physiotherapists. Whilst the application of national guidelines typically requires adaptation to local circumstances, it appears that in their study, this was not undertaken. Their costs of implementation of the guidelines among 18,000 physiotherapists show that whilst the dissemination of the physical guidance cost around €63000, further costs of around €24000 were required for preparing and undertaking training in support of the guidance.

It is also interesting to note that in the Hoeijenbos study, the treatments costs were not significantly altered by the guidance and so the costs of implementation are likely to change the guidelines from being broadly cost-neutral to cost-increasing. This serves to illustrate the fact that omitting development and implementation costs can lead to the

wrong conclusions being drawn. So, whilst the majority of studies gave conclusions highlighting that total costs had reduced, this may not be the case if the costs of development and monitoring had been included.

Clearly, in order to include the costs of development and implementation, additional data needs to be collected which will add to the costs of any evaluation. However, this need not be arduous when the protocol has a quite narrow focus. Robling and colleagues (2002), for example, was able to produce simple estimates around the costs of seminars given. Schmidt (2002), meanwhile estimated costs based on 'guesstimates', which whilst not being ideal, does allow an organisation to recognise that some non-treatment costs are necessary. A more detailed examination of the methods used to estimate development and implementation costs, and their results, is undertaken in the next section.

At the time of the literature search, a systematic review was identified that looked specifically at developing and implementing guidelines (Grimshaw et al. iii-iiv). That study had a different emphasis, focussing on what it termed 'rigorous' evaluations of guideline implementation. They identified 235 studies that evaluated the development and implementation of guidelines and within these, only four studies estimated the costs of development and implementation. Consequently, this reinforces our finding at development and implementation costs are rarely evaluated.

It should be noted that there was little overlap between the studies identified in this review and the review of Grimshaw *et al* (2004). Likewise, none of the four studies that estimated the costs of guideline development in Grimshaw *et al* (2004) were picked up in this review. In order to capture a wider range of studies, we subsequently updated the Grimshaw review which was limited to pre-1999 studies. The results of this work are reported in the next section.

5.1.4 Conclusion

The review highlighted the fact that 'implementation' is sometimes identified as the cost of the intervention, as opposed to the costs of preparing the staff and organisation for the initiation of the standardised care. For example, Cromwell identifies a cost associated with the implementation of a smoking cessation programme which is based around the provision of counselling and therapies to patients (Cromwell et al. 1759-66). Another problem is that studies frequently refer to development and implementation but this only takes place in a general narrative, without any attempt at quantifying the amount of resource devoted to it. Consequently, whilst a superficial look at the literature may suggest that implementation costs are widely estimated, this is not confirmed by a more in-depth appraisal.

The review also highlights the wide range of settings and conditions where protocols have been developed. The scope of the protocols vary widely from changes in prescribing a single medication, through to entire care pathways. This will make it extremely unlikely that any generalisable conclusions could be drawn from studies evaluating protocols. Even if the same protocol was adopted by different hospitals, it would probably be adapted and implemented in different ways. Likewise the treatment consequences are likely to differ between hospitals due to differences in baseline treatment patterns.

Consequently, the emphasis of the economic study shifted away from trying to study the cost-effectiveness of protocols within the case studies to the study of the costs of development in detail within the case studies. Such work was considered to be of greater value given the paucity of evidence in this area.

5.2 Costs of development and implementation

The review of economic evaluations of standardised care showed that very few studies had considered the costs of development and implementation within the evaluations. In order to assess these costs more fully, we gathered evidence from three further sources. Firstly, we used the results of the systematic review of Grimshaw and colleagues (2001) that examined the effectiveness and efficiency of guideline dissemination and implementation strategies. Three studies that reported the costs of development and/or implementation were taken from this review.

Secondly, we re-ran the Grimshaw search strategy for MEDLINE papers to cover the period 1999-2005. Their other search strategies were not undertaken due to the volume of hits reported in the original work (>150,000), which was considered unnecessarily large for the role of the search in this study. This search produced 7 papers that included costs relating to development and/or implementation. One of these, was picked up in the search of NHS EED reported earlier in this section and so is omitted from the review here as detailed costs were only available via personal communication with the author (Tilley et al. 143-49).

The third source for studies examining the costs of guideline implementation comes from a systematic review published after the review phase of this study had completed (Hoomans et al. 305-16). Whilst this is not within the timeframe of the reviews undertaken as part of this study, the work was considered important enough to require inclusion within study. The Hoomans systematic review used a different search strategy to that undertaken by ourselves and Grimshaw and covered the period 1998 to 2004. It identified 24 economic evaluations, including 15 that reported the costs of development and implementation strategies. All of these studies were retrieved, although four were subsequently excluded as they were not considered to evaluate standardised care programmes (Costanza et al. 39-46;Cowper et al. 327-32;Frenkel et al. 289-97); 'protocol' was used in the description of the study but not in the sense of describing a care pathway. Two further studies were excluded as their costs referred to the treatment itself, rather than the implementation of the guideline (Graff et al. 421-27;Kumana et al. 569-74). One further study was excluded as it referred to an education package that included training on the development of protocols (Kenkre et al. 675-81), and another two excluded as the standardised care was incidental to the main focus of the study and their costings (Teich et al. 2741-47).

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Table 5.1. Summary of economic evaluations of standardised care

Author	Country	Condition	Aspect of care	Dev.	Imp.	Cons.	Resource use and cost results
Perlstein	USA	Bronchiolitis	Assessment and treatment following admission to hospital	✗	✗	✓	Number of admission, length of stay, x-rays, antibiotic use reduced. Measurement of blood gases increased. Total costs reduced.
Al-Eidan	UK	Community-acquired lower respiratory tract infection	Inpatient prescribing	✗	✗	✓	Length of stay and treatment durations reduced. Total healthcare costs reduced.
Caragher	USA	Chest pain	Diagnosis in patients presenting to the emergency department	✗	✗	✓	Length of stay, laboratory procedures and total costs reduced.
Chau	Hong Kong	Myocardial infarction	Secondary prevention	✗	✗	✓	Prescriptions and monitoring increased. Cardio- and cerebrovascular events reduced.
Dhaliwal	India	Infertility	Treatment	✗	✗	✓	Drug and monitoring costs reduced.
Dryjski	USA	Deep vain thrombosis	Screening	✗	✗	✓	Test costs reduced.
Kirsch	USA	Coronary artery bypass grafting, laparoscopic cholecytectomy and lumbar laminectomy	Anaesthetics	✗	✗	✓	Drug costs reduced.
References	(Perlstein et al. 1001-07;Al-Eidan et al. 387-94;Caragher et al. 1434-39;Chau et al. 360-68;Dhaliwal et al. 295-99;Dryjski et al. 1010-15;Kirsch et al. 416-24)						
Notes	Dev= Protocol development costs included, Imp= Protocol implementation costs included, Cons= Protocol consequence costs included						

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Table 5.1 continued

Author	Country	Condition	Aspect of care	Dev.	Imp.	Cons.	Resource use and cost results
Lavenson	USA	Stroke	Screening	✗	✗	✓	Screening costs increased, treatment and total costs reduced.
Lotan	USA	Bladder cancer	Diagnosis/follow-up	✗	✗	✓	Total costs reduced.
McFadden	USA	Asthma	Assessment and treatment in patients presenting to the emergency department	✗	✗	✓	Length of stay in emergency department, number of admissions and intensive care unit admissions reduced. Total cost reduced.
Reilly	UK	Osteoarthritis	Recovery following knee arthroplasty	✗	✗	✓	Length of stay reduced, assessment costs and outpatient follow-ups increased. Total costs reduced.
Sanfield	USA	Diabetes	Screening/assessment for therapy escalation	✗	✗	✓	Screening costs increased, numbers initiation new therapy reduced. Total costs reduced.
Velde-Zimmermann	Netherlands	Melanoma	Detection of tumour cells in biopsies	✗	✗	✓	Material costs reduced.
Von Seggern	USA	Refractory migraine	Treatment with analgesics	✗	✗	✓	Emergency department and office visits reduced. Medication costs increased, total costs decreased.
Schiffman	USA	Asthma	Management of asthma in general practice	✗	✗	✓	Total costs increased.
Cromwell	USA	Smoking	Smoking cessation	✗	✗	✓	Counselling and prescription costs increased.
References		(Lavenson, Jr. et al. 638-43;Lotan et al. 75-79;McFadden et al. 651-61;Reilly et al. 351-57;Sanfield et al. 599-607;van der Velde-Zimmermann et al. 51-54;van der Velde-Zimmermann et al. 51-54;Von Seggern et al. 341-45;Cromwell et al. 1759-66;Shiffman et al. 767-73)					
Notes		Dev= Protocol development costs included, Imp= Protocol implementation costs included Cons= Protocol consequence costs included					

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Table 5.1 continued

Author	Country	Condition	Aspect of care	Dev.	Imp.	Cons.	Resource use and cost results
Jones	USA	Various	Non-steroidal anti-inflammatory drug prescribing	✗	✗	✓	Prescribing of expensive medications reduced. Total prescribing costs reduced.
Goode	USA	Cystitis	Treatment of uncomplicated cystitis in women	✗	✗	✓	Prescription medication and total direct costs reduced.
Tilley*	UK	Impacted third molars (wisdom teeth)	Extraction of impacted third molars	✓	✗	✓	Details of development costs not given. Total cost per patient increases.
Adrales	USA	Trauma	Insertion of thoracostomy tube	✗	✗	✓	Increase in the use of antibiotics, and reduction in number of chest x-rays.
Gomez	USA	Myocardial ischaemia	Emergency department diagnosis	✗	✗	✓	Length of stay and inpatient costs reduced.
Perlstein	USA	Acute gastroenteritis	Treatment of acute gastroenteritis in hospital	✗	✗	✓	Length of stay and total costs reduced.
Reddy	USA	Community acquired pneumonia	Treatment in hospital	✗	✗	✓	Length of stay, total costs and readmissions reduced.
Xakellis	USA	Pressure ulcers	Prevention of pressure ulcers in long-term care	✗	✗	✓	Costs of prevention increased, cost of treatment decreased, and total costs decreased.
Kollef	USA	Patients requiring mechanical ventilation	Weaning from mechanical ventilation	✗	✗	✓	Duration of mechanical ventilation reduced, total length of stay and costs were not changed.

References	(Jones et al. 926-30;Goode et al. 202-07;Tilley et al. 143-49;Adrales et al. 210-14;Gomez et al. 25-33;Perlstein et al. 20-30;Reddy et al. 1142-48;Xakellis, Jr. et al. 22-29;Kollef et al. 567-74)
Notes	Dev= Protocol development costs included, Imp= Protocol implementation costs included Cons= Protocol consequence costs included
*	Further details of implementation costs given in Table 24.

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Table 5.1 continued

Author	Country	Condition	Aspect of care	Dev.	Imp.	Cons.	Resource use and cost results
Bernstein	USA	Oncology	Use of filgrastim in the treatment of febrile neutropenia	✗	✗	✓	Duration of therapy reduced and drug cost per course of therapy reduced.
Stewart	USA	Patients undergoing endoscopic sinus surgery	Surgical instrumentation, preoperative and postoperative care	✗	✗	✓	Number of blood tests and overnight stays reduced. Total hospital costs reduced.
McLean	Canada	Asthma	Treatment by community pharmacists	✗	✗	✓	Reduction in medical visits and hospitalisations. Increase in the costs of prescriptions. Total costs reduced.
MacLaren	USA	Critical care	Sedation and analgesia	✗	✗	✓	No difference in length of time in intensive care or total drug costs.
Hedberg	USA	Patients undergoing bowel resections	Postoperative enteral feeding	✗	✗	✓	Reduction in the number of infections. Increase in the costs of dietician time and reduction in total costs.
MacLaren	USA	Critical care	Use of continuous neuromuscular blockade	✗	✗	✓	Reduction in total drug costs.
Fakhry	USA	Neurotrauma	Emergency treatment of patients with head injury in hospital	✗	✗	✓	Reduction in intensive care unit days, hospital days and total costs.
Boyter	UK	Chronic obstructive airways disease	Prescribing for infective exacerbations in hospital	✗	✗	✓	No reduction in length of hospital stay or length of antibiotic treatment. Cost of antibiotic treatment reduced.

References	(Bernstein et al. 1330-33;Stewart et al. 161-65;McLean et al. 195-202;MacLaren et al. 662-72;Hedberg et al. 802-07;MacLaren et al. 49-55;Fakhry et al. 492-99;Boyter et al. 403-09)
Notes	Dev= Protocol development costs included, Imp= Protocol implementation costs included Cons= Protocol consequence costs included

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Table 5.1 continued

Author	Country	Condition	Aspect of care	Dev.	Imp.	Cons.	Resource use and cost results
Williams	USA	Infertility	Ovulation and intrauterine insemination	✗	✗	✓	Reduction in drug use and number of tests. Reduction in total costs.
Robling*	UK	Various	Magnetic resonance imaging	✗	✓	✓	Cost per practice per general practitioner (GP) for dissemination via seminars was £1911. Cost per practice per GP for feedback was £1667. Costs of telephone access were £5 per request.
Urban	Canada	Ovarian cancer		✗	✗	✓	Increased costs of screening and diagnosis. Reduced costs of treatment. Increase in total costs.
Legood	UK	Pressure ulcers	Use of pressure-relieving devices	✗	✗	✓	Costs of devices increased, whilst treatment costs reduced. Total costs reduced.
Schmidt*	USA	High risk patients underdoing non-cardiac surgery	Treatment with perioperative beta-blockers	✗	✓	✓	Implementation in the first year cost $27310, and $16000 in subsequent years. Annual savings relating to treatment consequences estimated to be between $352464 and $503520 pa.
Hoeijenbos*	Nether-lands	Lower back pain	Physiotherapy	✗	✓	✓	Implementation costs were €87416 with no significant difference in treatment costs.

References	(Williams et al. 316-19;Robling et al. 402-07;Urban et al. 251-70;Legood et al. 307-14;Schmidt et al. 63-69;Hoeijenbos et al. 85-98)
Notes	Dev= Protocol development costs included, Imp= Protocol implementation costs included
	Cons= Protocol consequence costs included
*	Further details of implementation costs given in Table 5.3.

As all of the studies included in this review included costs of development and/or implementation by nature of the search and filtering strategies, the data abstracted is in much greater detail than that in Table 24. The results produced by Grimshaw (2001) were used as a template, with data on cost components, resource use and costs being abstracted. Results are split into development and implementation stages in order to aid interpretation (Tables 5.2 and 5.3, respectively).

5.2.1 Results

Only three studies were found that estimated the costs of developing protocols, two of which were previously identified by Grimshaw, with the additional study coming from the review of Hoomans and colleagues. A much greater amount of evidence was found relating to the costs of implementation and dissemination. 16 studies were found; 3 from the Grimshaw review, 5 from the update of their review, 7 from the Hoomans review and 3 from the NHS EED review described in the previous section (numbers add up to more than 16 as some papers were identified by more than one search).

Overall, the level of reporting was poor, with few details given. Price levels were not always given and so it is not possible to compare costs as the financial year on which they are based is unknown; consequently, no attempt was made to adjust them all to a single reference year. Another barrier to comparison/interpretation is that the units of measurement differ. Some costs relate to the total per guideline programme for the hospital/region/country, some relate to per patient costs, and some to per practitioner costs. Consequently, comparisons between studies must be made with the utmost caution.

5.2.2 Development costs

The main component of cost within these studies was staff time required for literature reviews and meetings. This time ranged from 20 hours for a simple protocol relating to medication (Gurwitz, Noonan, and Soumerai 359-64), to 399 hours for an urological referral guideline (Thomas et al.). Other costs included were travel costs which are important for primary care protocol development due to the geographical spread of practices, and consumables.

The reporting of cost components within these studies was highly variable. Some studies simply gave a total cost with few details of what was included and/or the methods used to calculate them. For those studies where details on the cost components were available, the main elements appeared to be staff time relating to education materials and training, printing/mailing of guidelines and the analysis/reporting of activity. Other miscellaneous items included travel and office expenses/consumables.

The studies included quite complex guidelines relating to entire treatment pathways (Foy et al. 726-33), and one looking at national implementation of a treatment guideline (Hoeijenbos et al. 85-98). Perhaps as a consequence of this, the costs of implementation appear higher than those for development, however, care must be taken over this observation due to the obvious differences between the two sets of studies.
The methods for collecting the data were not always reported, even for staff time which is perhaps the most important cost component. Notable exceptions to this were Baker

and colleagues, who collected much of their data from staff interviews (Baker et al. 548-50). Also, Schmidt and colleagues generated simple estimates using professional opinion; they simply allocated proportions of staff time to guideline-related work (Schmidt et al. 63-69).

The studies by Robinson and Baker are of note as they estimated the costs for more than one condition or location (Robinson et al. 19-26;Baker et al. 548-50). Whilst the study by Baker showed very little variation in costs between guidelines relating to asthma and angina, Robinson showed a marked difference when their thrombolysis algorithm was implemented in four hospitals.

The study by Mason and colleagues is of particular importance, for although it was not picked up in the NHS EED search, it includes an economic evaluation of a guideline, and illustrates a framework for incorporating development and implementation costs into an economic evaluation. However, whilst it incorporates implementation costs within its cost-effectiveness analysis, it is not clear whether development costs are included in their calculations.

5.2.3 General

In common with the NHS EED search it was found that many papers did recognise and describe the resources used to develop and implement standardised care, but this was not undertaken in sufficient detail to estimate costs. For example, Perlstein and colleague described the professions that made up the guideline development team in their study, the length of meetings, the tasks undertaken, and the review process (Perlstein et al. 1334-41). This indicates that whilst some of the costs associated with the process of development and implementation are recognised, the opportunity cost of the time involved is not factored into the evaluation of cost-effectiveness.

5.2.4 Discussion

Very few studies were available that assessed development costs. These were also restricted to relatively simple forms of standardising care; focusing on a single referral or treatment decision. None examined the full pathway for care for a particular disease. Consequently, the costs produced by these studies would be expected to be lower than those seen for more complex protocols.

Costs of implementing standardised care were more prevalent and typically gave much greater detail of the cost components involved. Comparison between studies is difficult due to differences in methods and units of measurement, however, staff time appears to be the largest cost component.

It is noticeable that the studies by and large tend to examine quite simple protocols relating to a single aspect of care. Of the more complex are the studies of Foy and Hoejinbos that examine the treatment pathway for very specific conditions – abortion and physiotherapy for lower back pain, respectively. No study examined the costs of developing and implementing standardised care for the management of a condition

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requiring multiple professions and treatment decisions, such as those characterised by NICE Guidelines.

5.2.5 Reasons for omission

The reason why so few papers estimate the costs of development and implementation, when the resources required are frequently described is unclear. We can only speculate as to why this is the case as no explicit reason was given in any of the studies.

One possible reason is that either the development is seen as part of the 'quality assurance overhead' included in all clinical services and so is recovered through charges to customers. This would fit in with the tone of many of the American studies, which focus on charges, and hence financial return. Alternatively, the costs of development and implementation could be considered to be trivial in comparison to the costs of the service consequences precipitated by the protocol/guideline. For example, in one study looking at the training costs of disseminating a guideline it is stated that '*as training is a one-off investment, the training cost ….would fall to near zero over time*' (Robling et al. 402-07).

Grimshaw and colleagues (2004) recognise that there may be situations where it may be legitimate to ignore some costs if there is evidence that they are likely to be negligible. However, as can be seen from this review, a body of evidence does not exist in the public domain that allows us to conclude what the costs of protocol development and implementation are.

5.2.6 Search strategy

We must consider whether the studies in this review represent a full picture of studies that are available. Four separate searches contributed to identification of the studies presented in Tables 5.2 and 5.3. Firstly a review of economic evaluations within NHS EED, which was primarily undertaken to answer the question in the previous section (i.e. to what extent are development and implementation costs included within economic evaluations of standardised care). Two pre-existing systematic reviews examining development and dissemination were also used. Finally, the older of the two reviews was updated.

The update, the NHS EED search and Hoomans review all used different searches strategies and sources, and included publications from the same time period. Interestingly, all contributed to the number of studies identified with little overlap. This highlights the difficulty of searching for studies of this nature; both the terms relating to standardised care and costs are used indiscriminately within many articles, and as a consequence when drawing from such a large pool of studies, different approaches produce different results. It is also clear that the approach used to screening studies can contribute to different results; 9 of the studies included in the Hoomans review were not considered to be evaluations of standardised care (as conceptualised in this report). Consequently, given the difficulties of searching for relevant studies in this topic area we can not be fully confident that all available evidence has been collected. However, the use of multiple search strategies gives us some confidence that a wide selection of

studies has been gathered that give a fair representation of the state of published evidence.

5.2.7 Other possible costs of standardised care

When this study design was first developed, it was hypothesised that standardised care may have other costs relating to staff discontentment with perceived restrictions to their role. So, for example, it was hypothesised that standardised care may indirectly increase staff turnover. No mention of this was made in any of the studies included in this review. Whether this hypothesised link exists and the size of its related cost, are therefore, unknown.

5.2.8 Other sources of data

Whilst not in the remit of the study, some additional work was undertaken to examine the costs of NICE guideline development. This was undertaken due to the lack of evidence relating to the costs of development, and the clear policy relevance of NICE guidelines to the current NHS. It is also important to consider that when national guidelines are implemented locally, the national costs can be easily ignored (as is the case in Hoeijbos (2005))

The work undertaken was quite simple, the costs of the NICE Guideline programme were compared against the number of guidelines produced. However, because the costs in any one year will also reflect ongoing work, we examined costs and published guidelines over five years; this will minimise the contamination of a single year's work-in-progress. The five years considered were 2002/3 through to 2005/6. All data were taken from Annual Reports. Over this time £31.2 million was allocated to clinical guidelines and the cancer service guidelines, with 57 guidelines being published amounting to an approximate cost per guideline of £550,000.

These estimates do not include local adaptation of guidelines. This work takes considerable time and effort, and has not been costed. Even without adaptation, one study of national guidelines in the Netherlands relating to physiotherapy for lower back pain found that implementation cost €87,000 in the first year. We can therefore safely assume that including the costs of local adaptation of guidelines would increase the cost per national guideline considerably.

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Table 5.2. Resource use and costs in the guideline development stage

Study	Area of resource use	Quantity of resource use	Total cost (unless stated otherwise)
Gurwitz*	Literature review by MD/pharmacist	20 hours	$650
Thomas*	GP/nurse/clinician researcher time spent at meetings	217 hours	£9029
	Research staff preparing for development meetings	182 hours	£2676
	Travel costs	Not detailed	£462
	Consumables	Not detailed	£3329
	Total		£15496
Raisch	Staff time developing guidelines and monitoring**	12 hours pharmacist, 3 hours physician, 36 hours support staff	£1213

References	(Gurwitz, Noonan, and Soumerai 359-64;Thomas et al.;Raisch et al. 1274-80)
*	Adapted from Grimshaw *et al* (2001)
**	Includes an indeterminate amount of time relating to monitoring which should be classified as an implementation cost

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Table 5.3. Resource use and costs in the guideline dissemination and implementation stage

Study	Area of resource use	Quantity of resource use	Total cost (unless stated otherwise)
Gurwitz*	Educational materials		
	Documentation preparation by MD/pharmacist	Included in development costs	Included in development costs
	Review of medical records by MD/pharmacist	25 hours	$813
	Printing costs	Not detailed	$200
	Educational meetings		
	Preparation time by MD/pharmacist	5 hours	$33
	Group discussions attended by staff	Not detailed	Not detailed
	Total		$1046
Thomas*	Educational materials		
	Consumables	Not detailed	£2484
	Time spent assembling and mailing the guidelines	24 hours	£265
	Postage of guidelines and letters	Not detailed	£431
	Educational meetings		
	Clinician time spent at meetings	111 hours	£7024
	Research staff preparing for meetings	40 hours	£517
	Travel costs	Not detailed	£304
	Total		£11025
Winickoff*	Computer time used to create reports	90 hours	$2300
	Staff time to produce reports	5-10 hours	$28-$55
	Total		$2328-2355

References	(Gurwitz, Noonan, and Soumerai 359-64;Thomas et al.;Winickoff et al. 43-46)
*	Adapted from Grimshaw *et al* (2001)

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Table 5.3 continued

Study	Area of resource use	Quantity of resource use	Total cost (unless stated otherwise)
Lock	Postal marketing		
	Staff costs	Not detailed	£128
	Travel	Not detailed	£0
	Postage	Not detailed	£101
	Telephone	Not detailed	£19
	Consumables	Not detailed	£296
	Total		£543
	Telemarketing		
	Staff costs	Not detailed	£164
	Travel	Not detailed	£0
	Postage	Not detailed	£92
	Telephone	Not detailed	£66
	Consumables	Not detailed	£449
	Total		£771
	Personal marketing		
	Staff costs	Not detailed	£90
	Travel	Not detailed	£4564
	Postage	Not detailed	£12
	Telephone	Not detailed	£52
	Consumables	Not detailed	£296
	Total		£5014

References	(Lock et al. 695-98)	

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Table 5.3 continued

Study	Area of resource use	Quantity of resource use	Total cost (unless stated otherwise)
Wong	Staff training	Not detailed	Not detailed
	Posters	Not detailed	Not detailed
	Total		$46 per patient
Verstappen	Feedback reports	Not detailed	€3317
	Quality meetings	Not detailed	€6427
	Physician time	Not detailed	€39270
	Continuation activities	Not detailed	€2484
	Software development for monitoring	Not detailed	€1000
	Revision of guidelines	Not detailed	€377
	Total		€52875
Bahrami	Computerised aided learning (education)	Not detailed	£482 per practitioner
	Audit and feedback	Not detailed	£217 per practitioner
Hoeijenbos	Guideline materials design	Not detailed	€12302
	Printing	Not detailed	€33534
	Mailing	Not detailed	€17265
	Preparation for training	Not detailed	€10723
	Training	1 x 1 evening plus 5 x 2 evenings	€12596
	Administration for training	Not detailed	€996
	Total		€87416

References (Wong et al. 29-33;Verstappen et al. 391-98;Bahrami et al. 691-96;Hoeijenbos et al. 85-98)

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Table 5.3 continued

Study	Area of resource use	Quantity of resource use	Total cost (unless stated otherwise)
Ansari*	Data collection		
	Photocopying and data entry	-	£29
	Identification of patients	15 mins pharmacist per patient	£1807
	Co-ordination	1 hour senior pharmacist per month	£214
	Data analysis		
	Development of database	6 mths statistician	£9639
	Analysis and report writing	5 days statistician	£419
	Supervision	6 hrs consultant per month	£2592
	Meetings	2 meetings	£432
	Total		£15143
Delate	Prescription guidance and letter to physician**		
	Information systems, programming time, clinical review time and postage	Not detailed	$3
Foy	Development, dissemination, implementation (including audit and feedback)	Not detailed	£53742

References	(Ansari et al. 842-48;Delate et al. 396-403;Foy et al. 726-33)
*	These refer to the first year of the guidelines. Costs for subsequent years were also estimated at £4990 per annum.
**	Represents a total cost for a separate arm of a trial.

The Contribution of nurses, midwives, and health visitors to protocol-based care and its variants,
and the impact of their contribution on patient and staff outcomes, quality and costs of care

(SDO Project 08/1405/079)

Table 5.3 continued

Study	Area of resource use	Quantity of resource use	Total cost (unless stated otherwise)
Baker*	Purchase of national guideline materials	Not detailed	£29-32
	Adaptation of guidelines	Not detailed	£10-10
	Data collection	Not detailed	£152
	Feedback	Not detailed	£18
	Audit	Not detailed	£10-10
	Total		£180-180
Gomel	Postal marketing		
	Staff costs	Not detailed	A$987 per 100 physicians
	Travel	Not detailed	A$0 per 100 physicians
	Postage	Not detailed	A$112 per 100 physicians
	Telephone	Not detailed	A$0 per 100 physicians
	Consumables	Not detailed	A$651 per 100 physicians
	Total		A$1750 per 100 physicians
	Telemarketing		
	Staff costs	Not detailed	A$1027 per 100 physicians
	Travel	Not detailed	A$0 per 100 physicians
	Postage	Not detailed	A$0 per 100 physicians
	Telephone	Not detailed	A$50 per 100 physicians
	Consumables	Not detailed	A$0 per 100 physicians
	Total		A$1077 per 100 physicians

References	(Gomel et al. 203-11;Baker et al. 548-50)
*	Represents figures for two separate guidelines (asthma and angina)
A$	Australian dollars

The Contribution of nurses, midwives, and health visitors to protocol-based care and its variants,
and the impact of their contribution on patient and staff outcomes, quality and costs of care

(SDO Project 08/1405/079)

Table 5.3 continued

Study	Area of resource use	Quantity of resource use	Total cost (unless stated otherwise)
Gomel	Academic detailing		
	Staff costs	Not detailed	A$4046 per 100 physicians
	Travel	Not detailed	A$1600 per 100 physicians
	Postage	Not detailed	A$0 per 100 physicians
	Telephone	Not detailed	A$23 per 100 physicians
	Consumables	Not detailed	A$227 per 100 physicians
	Total		A$5896 per 100 physicians
Merlani	Staff time including meetings, teaching and reviews**	Not detailed	£31502
Robling	Training via seminars	1 seminar	£80 per physician
	Feedback	Not detailed	£62 per physician
Schmidt	Clinical champion	10% in first year (5% thereafter)	$12000 ($6000)
	Clinical support	20% surgical case manager pa	$10000
	Computer programming costs	Not detailed	$4185
	Printing and mailing	Not detailed	$1125
	Total		$27310 ($16000)

References	(Gomel et al. 203-11;Merlani et al. 620-24;Robling et al. 402-07;Schmidt et al. 63-69)
*	Represents the mean of two sets of guidelines (asthma and angina)
**	It is unclear from the article whether the additional time relating to treatment is also included.
A$	Australian dollars

The Contribution of nurses, midwives, and health visitors to protocol-based care and its variants,
and the impact of their contribution on patient and staff outcomes, quality and costs of care

(SDO Project 08/1405/079)

Table 5.3 continued

Study	Area of resource use	Quantity of resource use	Total cost (unless stated otherwise)
Mason	Guideline materials	Not detailed	$5550
	Training and recruiting staff	Not detailed	$4830
	Training facilities hire	Not detailed	$5430
	Implementation coordinator	Not detailed	$33225
	Pharmacist training	Not detailed	$10185
	Pharmacist outreach	Not detailed	$31725
	Total		$90945
Robinson*	Cost per meeting		
	Preparation time	Not detailed	£374-498
	Attendance time	Not detailed	£282-410
	Materials	Not detailed	£5
	Compliance time	Not detailed	£188-328
	Total		£842-1201
	Total cost of meetings	Not detailed	£3370-4803
	Initial set up costs	Not detailed	£323-354
	Overall costs		£3693-5157

References	(Robinson et al. 19-26;Mason et al. 2988-92)
*	Costs were calculated for four hospitals with figures given for the cheapest and most expensive

5.3 Conclusions

The review of NHS EED shows that the costs of protocol development and implementation are rarely included in economic evaluations of protocol based care. Using a strict definition of economic evaluation, as operationalised by the NHS Economic Evaluation Database, only 2 out of 42 evaluations included such costs. This is despite the fact that the resource implications are recognised by researches as highlighted by the frequent description of the protocol development process in the articles (and the existence of the article itself, which requires evaluation of the protocol's effect).

Utilising and updating previous work that has specifically examined dissemination and implementation strategies identifies more studies that have examined these costs, but the prevalence of such work is still low; 16 studies were identified. Producing specific conclusions relating to the magnitude and nature of protocol development and implementation costs is difficult due to differences in costing method methods and report. For example, cost components are not always reported, price levels are not always reported, and the unit of measurement varies betweens studies (e.g. total costs, per patient costs, per practitioner costs).

We can tentatively conclude that:

- Development costs are particularly scarce in the literature, despite the process being described in outline in many studies.

- Staff costs appear to a major cost component in both the development and implementation of standardised care.

- There appears to be a feeling that development and implementation costs are considered negligible compared to the costs of treatment consequences.

- Inclusion of development and implementation costs can have a significant effect on the conclusions of studies.

- Evaluations have tended to focus on simple protocols/guidelines that relate to a simple set of treatment and referral decisions. No costs are available for more complex treatment guidelines covering the complete management of a condition.

- The costs of development and implementation are likely to vary widely between locations.

- The NICE guideline programme consumes considerable resources, even if the national guideline programme is considered – around £6.2 million per annum, or £550,000 per guideline. Including the costs of local adaptation of guidelines is expected to increase this cost considerably.

Appendix 5b: Economics Reference list

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Appendix 6a: Economic case studies

6.1 Introduction

The time and effort required to develop standardised forms of care is substantial, but very little information is available on these costs. The literature review showed that few economic evaluations gathered data on the costs of protocol development and implementation; the costs associated with protocol development were especially sparse. From those studies that were available, it can be seen that staff costs are perhaps the largest component of development/implementation costs. Consequently, we aimed to collect data from case study sites relating to these resource intensive activities through a series of interviews and questionnaires to staff members. These data would then be used to assess the costs of development and implementation.

Within this overall approach, data would also be used to map out which types of staff took part in the pathway development teams, and how their various talents were used throughout the process. This would therefore add to the other data collected as part of the case studies by highlighting the role of nurses, midwives and/or health visitors in the development/implementation process.

6.2 Methods

In the economic analysis three case study sites were assessed. For each site we identified an existing pathway that had been implemented which formed the basis of the costing exercise and hence the data collection. The sites and pathways were the same as those used in the non-economic case studies, and were as follows:

Nursing

Case study - Integrated care pathway for myocardial infarction (MI)

Case study - Liverpool Care Pathway (LCP)

Health visiting

Case study – Maternal mental health protocol

In one other site we were unable to secure the cooperation of the lead person for the economic study. In the other site, the development of the target guideline was delayed by about twelve months and then it was envisaged that the development would take another 12 months. This meant that our data collection would be incomplete at the end of our study period, and therefore the economic analysis was dropped from that case study.

Research ethics and research governance approvals were gained from each site before data collection proceeded. All staff that were approached were given participant information sheets relating to the economic study, and asked for consent to their participation in the economic study.

6.3 Data collection

Data were required on who was involved and their level of input. Initially, these data were to be captured through a series of structured interviews. An interview schedule was developed and piloted, that elicited information on the characteristics of the interviewee, their input into the stages of protocol development in terms of the individual tasks and the time spent on each one. Other contextual information was also gathered on such issues as whether the time was included in a job-plan or not.

It was planned that this information would be gathered through a cascade approach. In the first instance the site lead would be interviewed and within the interview other members of the team would be named along with their contact details. These named individuals would be contacted and interviewed. They would also be given the chance to identify any additional team members and again these individuals would be sought out and interviewed upon giving their consent.

In practice, however, the aforementioned method of data collection yielded very little information. This was due to a number of limiting factors. The main limiting factor was the inability to set up interviews with members of the team either because they were unwilling to participate in the study, or they did not respond to the invitation to take part in the study or they had left the organisation. This was partly due to length of time that had elapsed since the events took place, which in many circumstances, was several years.

As a consequence of these problems, we developed an alternative approach which was based on in depth interviews with the site leads, together with analysis of documentary data. The documents that were used mainly comprised of minutes of team meetings and cost estimates for external services. The data extracted from the interviews and documentary evidence were as follows:

1. All the team members, their grade and their professional grouping

2. The meetings that took place how often and their duration

3. The training that was involved, who and how many people attended the training sessions and whether there were any supporting documents

4. How many drafts of the pathway there were and if there was any, who were involved in monitoring it and any supplementary documentation.

6.4 Analysis

From the above information we aimed to produce the following analysis outputs: a) the total amount of time the process took split by staff group and by year, b) the total cost of the pathway process split by staff group and by year, and finally c) the total cost of each phase of the pathway process; development, implementation, and monitoring.

The daily cost of different staff were taken from Curtis (2007), and are summarised in Table 6.1. To help our ability to assess the degree to which different staff groups contributed to the development process, staff were allocated to four groups: Group 1 incorporates managers and administrative staff, in Group 2 are consultants, Group 3 represents nurses, midwives and health visitors, and Group 4 are any other medical staff such as paramedics. For staff who fall into Group 4 daily costs are fixed to the midpoint of Agenda for Change grade 6.

Total resource usage and costs were then aggregated across groups to derive the total number of days each group of individuals spent on the pathway split by year. The total cost per group was also calculated split by year. Finally, in order to approximate the cost of each phase of the protocol process we summed up the staff costs attributed to development, implementation and monitoring. As this requires an aggregation of costs over the years discounting of costs is required to g*et al*l costs in terms of their present values. We therefore discounted costs at 3.5 per cent as recommended by the National Institute for Clinical Health and Excellence (NICE 2004).

Table 6.1. Costs per day of staff time

Staff	Cost per day* (£)	Source
Nurses		
Nurse team manager (including ward managers, sisters and clinical managers)	**230**	**PSSRU 2007**
Nurse team leader (includes deputy ward/unit manager, ward team leader, senior staff nurse)	**200**	**PSSRU 2007**
Nurse/Day ward (includes staff nurse, registered nurse, registered practitioner)	**165**	**PSSRU 2007**
Health Visitor		
Health visitor	**224**	**PSSRU 2007**
Doctor		

Consultant: medical	1054	PSSRU 2007
Consultant: surgical	1054	PSSRU 2007
Consultant: psychiatric	1058	PSSRU 2007
Administration		
Management/administration	230	PSSRU 2007

* Costs include salaries, on-costs, overheads and include allowances for training.

6.5 Results

6.5.1 Nursing: Myocardial infarction pathway

Two interviews were undertaken in this site in relation to the economic analysis. The first was done with the site lead and the second was done with the main clinician involved in the development of the pathway. The documentary evidence was used to help with the costing exercise were the minutes of meetings dating from the start of the protocol development process in 2000 through to 2005. These minutes consisted of full team meetings as well as subgroup meetings. These documents highlighted the tasks assigned to different individuals as the pathway progressed over the years. The numbers of meetings are presented in Table 6.2. There were 19 meetings in total over the 6 year period where documentary evidence was available.

Table 6.2. **The number of meetings held over the six year period to develop, maintain and review the myocardial infarction care pathway**

| Year:	2000	2001	2002	2003	2004	2005
Number of meetings:	4	4	3	3	3	2

With these two sources of data we were able to map out the profile of resources that the pathway took up and link together which individuals did which tasks in the form of a 'task list'. Once the task list was written up the site lead was sent a copy of the task list and was asked to check that it was an accurate representation of what went on, and if there was anything they would like to add to it. Once this was agreed the site lead was asked to estimate the time it took the relevant individual to complete a given task. The majority of tasks were carried out by the site lead or the site lead was involved indirectly meaning that these estimates were from a reliable source. Once this was complete we were able to pool together the data and calculate the total number of full days per group as well as the total cost per group. For each individual the total number of full days was aggregated and multiplied by the relevant cost per day to produce an estimate of the cost of their input. The results are shown in Figure 6.1.

In Figure 6.1 we can see that the profile of activity over the years is greatest in the first two years and then subsides, however, an identifiable staff input is still required 8 years

after the protocol was initially developed. It can be seen that in the first two years the majority of days dedicated to the protocol were from managers and nurses (groups 1 and 3). This represents the time spent on the protocol development by the protocol coordinator and the lead nurse on the protocol. In support of the pathway development in year 1, a one day stake holder event was organised where the pathway was promoted where there were approximately 60 attendees. This is represented in the large number of days represented by group 4 in year 1.

Figure 6.1. Total number of days per group by year (MI care pathway)
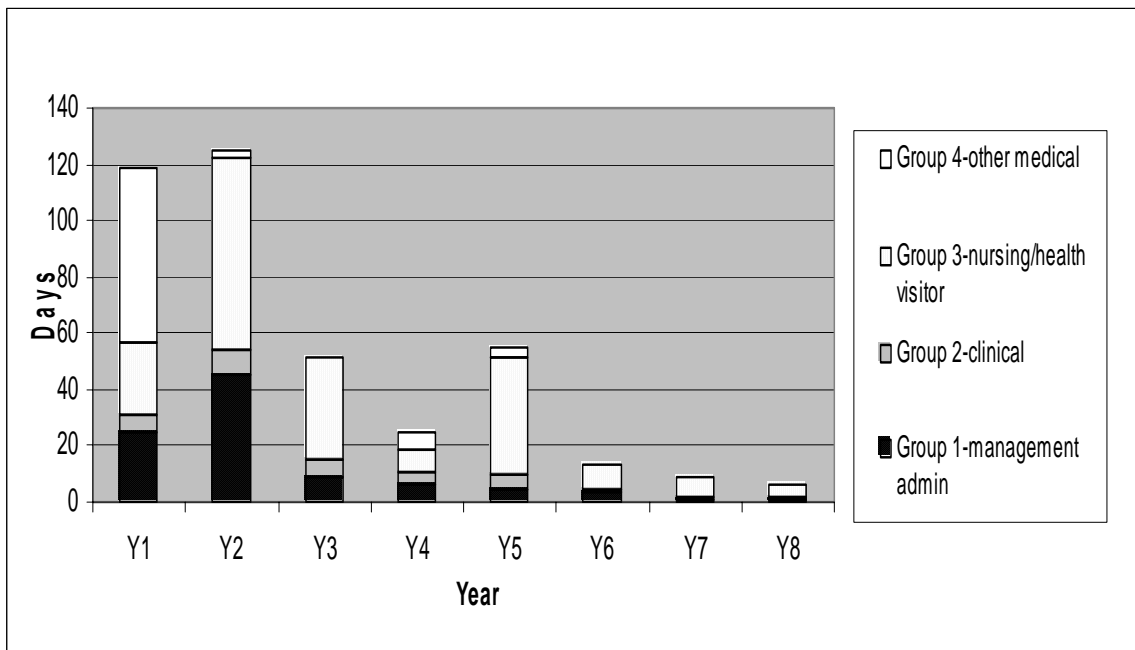
Years 2 to 8 were dedicated to implementing and monitoring the pathway. There were several audits that took place which fed into the redrafting of different versions of the pathway. Also training sessions took place to nurses and doctors in different wards. Supplementary training materials were prepared in line with training needs. Initially the protocol was rolled out in the Coronary Care Unit (CCU) and this was followed by one other cardiac related ward. Attempts were made to roll out the protocol into the more general wards as the protocol became a more accepted standardised hospital document, however these attempts proved unsuccessful. The protocol has thus been fully implemented in two of the hospital's wards to date.

The overall costs per year are shown in table 6.3. After discounting (see Methods), the total cost of the pathway was £100,823. The largest share of this was taken up by the monitoring phase costing approximately £42,252 (42%) of the total cost with implementation and development costing £31,016 (31%) and £27,555 (27%), respectively.

Table 6.3. Overall costs, when combined with daily staff costs, of the development, implementation and monitoring of the MI care pathway

Year:	1	2	3	4	5	6	7	8
Costs :	£27,555	£33,746	£15,875	£8,854	£15,501	£3,616	£2,661	£2,169

6.5.2 Nursing: Liverpool end of life care pathway

The economic analysis of this case study site was based on the interview from the site lead. The lead was involved with the pathway from the beginning, overseeing the piloting of the pathway in one ward and guided its implementation in other wards. We were, however, limited in the amount of information we could take from this site relating to the economic analysis for the following reasons: a) there was not any relevant supplementary documentary evidence that was available, and b) the individual who was employed to solely work on the pathway no longer worked in the hospital.

We were able to create a task list based on the interview with the site lead and from this we were able identify key events from the start of the pathway in 2001 until the present. A key event within this site was their ability to attract funding on two occasions to allow a post for a key individual to lead the pathway implementation across the hospital wards. In the first instance the post was funded for 1 year and this was then extended by 3 years by a different source of funding.

The majority of the resources used in this protocol were tied to the funding of the individual that was to lead the pathway. From the interview, however, it was also highlighted that additional resources were dedicated to the pathway. The interview allowed us to derive a task profile and the resources linked to each task (in terms of which individual was concerned with completing the relevant task). We were thus able to estimate the results that are shown in Figure 6.2.

As was previously stated, some of the detailed information in this site was unavailable because of staff leaving and the lack of relevant documentary evidence. Thus we had to aggregate the activity of years 4 to 5 and 6 to 8 because whilst we had information about what tasks took place, we did not have specific information as to the specific year that each task took place.

Unsurprisingly from Figure 6.2 we can see that the majority of the activity took place when the funding was in place, although the preceding years did see work done to successfully secure the funding. In the first and second years the site lead and her colleague attended a 2 day study day, which was followed by the pilot study where the pathway was implemented into one of the hospital wards. From the positive results that followed from this, funding was successfully sought (on two occasions) to employ someone to further implement the pathway into other wards. From the positive results that followed from this, funding was successfully sought (on two occasions) to employ someone to further implement the pathway into other wards. As resources were limited

in these first years, there was a limit in the amount of time that could be dedicated to the protocol. Notwithstanding, however, time was put aside to do the pilot study and write up the funding bid in addition to the study days. This was also helped by the fact that the pathway did not require much adaptation. The main task that was required was the training of medical staff in its use.

Figure 6.2. Total number of days per group by year (LCP case study)
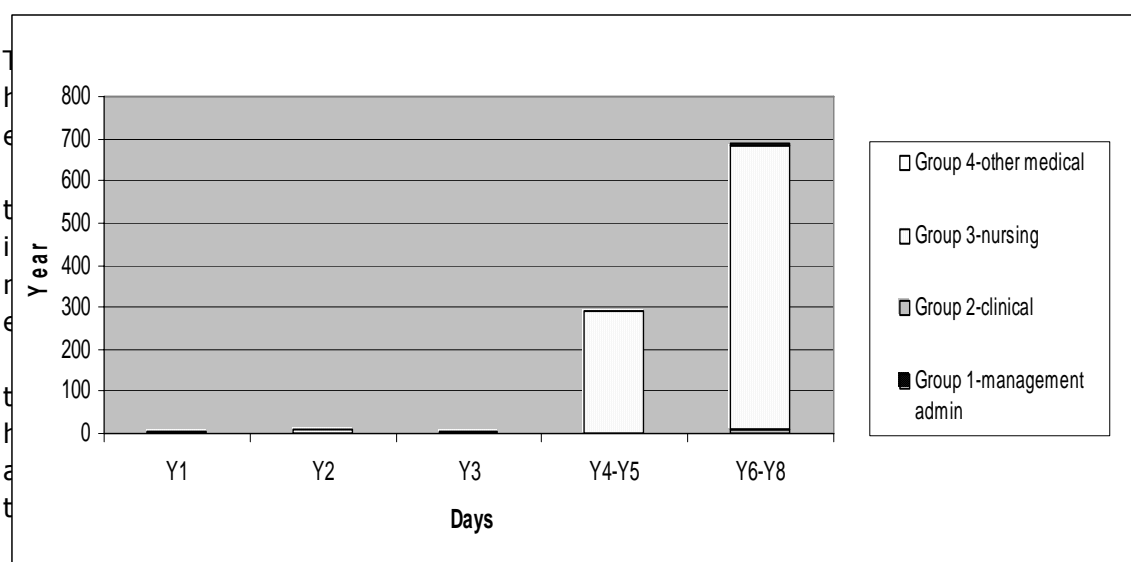
The time that the nurse who took up the pathway co-ordinator role spent on the protocol is highlighted by the high proportion of days shown in years 4 to 5 and years 6 to 8. In addition to this, other members of the Palliative Care Team supported the training sessions that took place to aid the implementation of the pathway. The final three years saw a change to the pathway which required input from other medical personnel.

The estimated cost of the pathway, derived from combining the staff costs with the days of pathway related work, are shown in table 6.4.

Table 6.4. Overall costs for the implementation and roll-out of the Liverpool end of life care pathway.

Years:	1	2	3	4-5	6-8
Costs:	£1,383	£2,190	£691	£45,273	£117,688

In the first three years, time was spent learning about the pathway, piloting it and writing the funding bid. Little work was required in these initial stages to adapt the pathway. In the fourth year there was a large increase in costs when the post was filled and additional resources were dedicated to the pathway in terms of delivering training, further championing of the pathway and finally managing the post holder. The final three years were the most costly. In addition to paying the post holders salary, additional costs

were incurred in updating of the pathway, delivering the requirements for the national review, more training, producing supporting documentation and again management.

We can see that the cost of the pathway is on the whole driven by the individual who filled the post the funding provided for. In addition to this, however, costs were also incurred from other supportive activities. Right from the start, most of the tasks were completed by individuals who fall under group 3 i.e. nursing.

With the limited amount of detail that was available to us the total cost of the pathway after discounting to produce a present value was £140,985 with each phase of the pathway costing the following: development = £1,383 (1%), implementation = £133,368 (98.55%) and monitoring = £6,234 (0.5%). This shows that nearly all of the costs fall under implementation, which makes sense as training played such a major role in the successful implementation of this protocol. Indeed no member of staff was permitted to use the protocol documentation before undergoing formal training. Likewise, development costs are so low as the pathway had been previously developed elsewhere and underwent very little adaptation to the case study site.

6.5.3 Health visiting: Maternal mental health protocol

In this case study an interview took place with the site lead for the economic analysis. In addition to this we had access to documentary evidence to supplement the information we derived from this key interview. The documentary evidence was made up of both the minutes of meetings and costings for an external trainer to supervise training sessions. In addition, a number of e-mail correspondences relating to the aforementioned training sessions were also available. The minutes dated back to the very first meetings of the core protocol group from 2004 to the most recent meeting in 2008.

As in the previous case the minutes highlighted the tasks assigned to different individuals in the group as the protocol progressed over its different stages. The meetings that took place are presented in Table 6.5.

Table 6.5. **The number of meetings held over the five year period to develop, maintain and review the maternal mental health protocol.**

Year:	2004	2005	2006	2007	2008
Number of meetings:	3	4	3	4	1

In summation there were 15 meetings in total (which were supported by documentary evidence) over the 5 year period.

As in the previous cases a task list was derived from collating the two sources of information. This site particularly showed the complexities of the protocol process. Here the protocol went through three stages, in this analysis we account for the final two to date. In the first stage (which precedes the time frame of our analysis) a protocol was developed, but was not actively implemented. In the second stage this pre-existing protocol was updated starting in 2004 (where our analysis begins), which was then

implemented. The final stage follows the PCT restructuring (merging several different localities into one) which took place in 2007 resulting in a) the trust wide harmonization of the protocol and b) the incorporation of the new NICE guidance into the harmonized protocol. This means that there were two distinct parts to this case study over the period that we observe (2004 – 2008) which is reflected in the results.

When estimating time inputs we split members of the team into core members and non-core members (based on information from the site lead and attendees of meetings) and used the information that we acquired from interviews to approximate how much time each spent overall on protocol related tasks. We deduced that members in the core group spent on average 2 hours a week on protocol related tasks whilst the non-core member spent 2 hours a month. From this we were able to estimate the results shown in Figure 6.3.

Figure 6.3. Total number of days per group by year (health visitor case study)
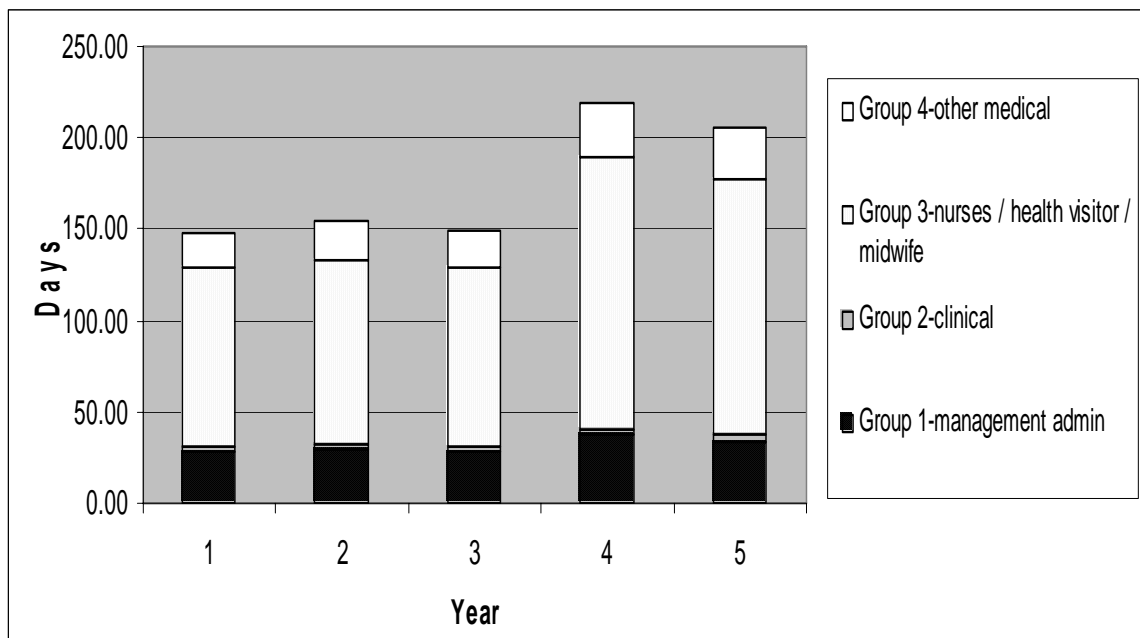

Figure 6.3 shows a steady profile of activity over the years with a sharp rise in activity in years 4 and 5 after the PCT restructuring took place. This reflects the merging of three separate localities into a single PCT, and the time required to update and implement the protocol across the new Trust.

The largest pool of activity was undertaken by the members of group 3 whilst there was very little input from individuals that would fall into group 2. As is the case in the previous case studies the individuals in group 3 represent the greatest pool of resources

Once costs are combined to the number of days, the following total costs were estimated, as shown in table 6.6.

Table 6.6. Overall costs for the development, implementation and review of the maternal mental health protocol.

Year:	1	2	3	4	5
Costs:	£33,150	£34,471	£34,387	£47,920	£45,101

We can see that the most costly years are years 4 and 5 post PCT restructuring where the protocol harmonization and trust wide implementation is taking place.

Finally, we estimate the total cost of the protocol as £176,098, with development, implementation and monitoring costing £65329, £110769 and £0.00 respectively. It should be noted however that over the 5 years the detail of information available did not allow the identification of resources dedicated to monitoring. We were only able distinguish between development and implementation costs, with the former covering years 1 and 2 and the latter spanning over years 3 to 5.

6.5.4 Discussion and conclusions

The case study work highlighted the difficulty in identifying staff time relating to protocol development, implementation and monitoring. These data are not routinely collected, and can only be constructed through a careful analysis of documentary evidence in tandem with detailed interviews with key personnel. More accurate estimates are only possible through prospective data collection during the protocol process; such an approach was not feasible in this project where our work was restricted to sites that had already established their protocols.

The three sites produce different profiles of costs, and the reasons for this need to be understood. Firstly, the methods and data available at the three sites differed slightly. This will have contributed to some of the findings, for example, the lack of monitoring costs in health visitor case study. Secondly, the nursing MI care pathway involved the development of a pathway in-house, whilst the nursing Liverpool Care Pathway (LCP) used a pre-existing pathway to a greater extend. Consequently, the nursing MI case study shows that development is associated with the greatest amount of input, whilst the other case studies do not. Thirdly, local factors play a big role in the resourcing of the development process. This is highlighted in the nursing LCP case study by the low staff input up until funding was found for a pathway coordinator, and in the health visitor case study by the increase in costs associated with the PCT restructuring which precipitated further amendments to the protocol.

The high cost of development seen in the nursing MI care pathway is of great importance. Within the literature review, such costs were the least researched of all costs relating to protocols. This case study shows that these can be significant, and exclusion of these costs from any evaluation of a new protocol is potentially a major flaw in any evaluation.

The results also show other important features. Of particular note is the level of staff input and costs; hundreds of days of staff time are required, and whilst this subsides over time when the protocol has been embedded in practice, some staff time is still required (see nursing MI care pathway). Also, as highlighted above, other events may precipitate further peaks in staff input, for example, rolling out the protocol, organisational restructuring, or the issuing of new guidance relating to the same clinical area. It appears that once the protocol is in place, its associated machinery needs to be brought back to life when changes occur in and around it.

Also of note in the three case studies is the prominent role given to nursing and health visitor staff in the development and implementation of protocols. Whilst we can make no claim as to the generalisability of this finding – in fact, we may expect a bias in favour of this finding as sites were recruited on the basis of their interest in nursing/midwifery – it highlights the important role that these staff groups can make to the protocol process.

In conclusion, this work shows that large amounts of staff time are required for the development and implementation of protocols. When interpreted in tandem with the results of the economic literature review, it is clear that these costs will make protocols less cost effective than initially envisaged. It also appears that in a rapidly changing healthcare environment, additional costs are generated for pre-existing protocols as they have to be adapted to incorporate many of these changes (e.g. organisational boundaries, or new associated guidance). When new forms of standardised care are developed, the anticipated staff input needs to be clearly identified, with due regard given to the longer terms costs associated with monitoring which can extend for many years into the future. Such costs can then be incorporated into an explicit evaluation of whether the protocol/guideline is likely to be cost-effective, for example, using the framework developed by Mason *et al* (2001).

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Appendix 6b: Interview guide resource use
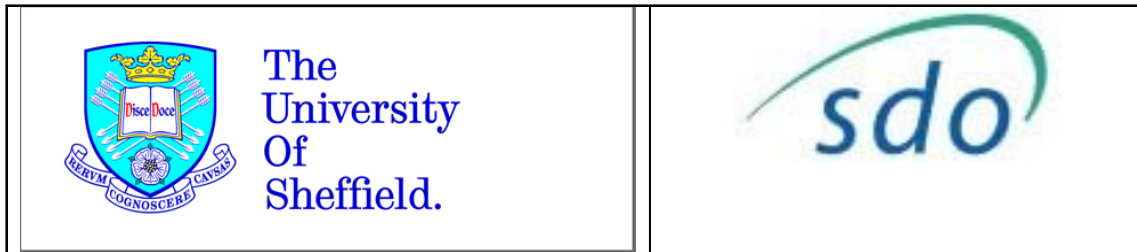
INTERVIEW GUIDE RESOURCE USE COSTS

Indicative questions for structured interviews with nurses and other staff to identify the costs of developing, implementing and monitoring 'standardised care.' The initial interview will be undertaken with the operational lead, with other personnel being identified from that initial interview, and the subsequent interviews with staff. In essence the list of interviewees will be self generated - a snowballing sample - by the interviewees themselves, and will map out the full range of staff involved in the guideline process.

Background
1. Name:

2. Post at time of care pathway development:

3. Professional group:

4. Grade:

5. Professional background:

Estimating the costs:
6. Trust name:

7. Name of the integrated care pathway:

8. The length of the development, implementation and monitoring processes

    a. When did the care pathway development process begin?

    b. When was the pathway implemented?

    c. Was the impact of the pathway formally monitored?

        i. How was it monitored?

        ii. How often was it monitored?

        iii. Is this process open-ended?

9. Personnel involved in the development stage.

    a. Names and post of people involved

10. Personnel involved in the implementation stage.

    a. Names and post of people involved

11. Personnel involved in the monitoring stage.

    a. Names and post of people involved

12. Identification of the tasks involved in the development stage.

    a. What meetings were put in place?

    b. Were specific milestones identified?

    c. Who was identified for producing specific outputs?

    d. Did informal discussions play a big role in this process?

13. Identification of the tasks involved in the implementation stage.

    a. What meetings were put in place?

    b. Were specific milestones identified?

    c. Who was identified for producing specific outputs?

    d. Did informal discussions play a big role in this process?

14. Identification of the tasks involved in the monitoring stage.

    a. What meetings were put in place?

    b. Were specific milestones identified?

    c. Who was identified for producing specific outputs?

    d. Did informal discussions play a big role in this process?

15. Estimation of the time spent on each task in the development stage

    a. How much of your time was spent preparing and attending meetings, informal discussions and producing the specified outputs?

16. Estimation of the time spent on each task in the implementation stage

    a. How much of your time was spent preparing and attending meetings, informal discussions and producing the specified outputs?

17. Estimation of the time spent on each task in the monitoring stage

    a. How much of your time was spent preparing and attending meetings, informal discussions and producing the specified outputs?

Appendix 7: Framework for an economic appraisal of standardised care

7.1 Introduction

Whilst the principles of economic evaluation of health care are well established, we have shown that the number of economic evaluations of protocols is small. Furthermore, the number that have taken full account of development, implementation and consequences within these evaluations is negligible. Within this study, we originally planned to evaluate the cost-effectiveness of a protocol in each of the case study sites by developing decision analytic models that mirrored the protocols' key decisions and then evaluating the costs and outcomes before and after the protocol was implemented. A previous evaluation looking at a protocol relating to the follow-up of patients with carcinoma of the bladder was seen as a good template for this approach (Lotan, Roehrborn, Lotan, & Roehrborn, 2002). Whilst the study by Lotan and colleagues did not include the costs of development and implementation within their evaluation, we planned to add simple estimates of these to our models, thereby producing complete evaluations in each of the case study sites. From this work it was hoped that we could produce recommendations that would be useful for future evaluations of standardised care.

However, several problems were encountered when this approach was being developed. Firstly, there were logistical problems in the case study sites that made the evaluations difficult to undertake. For example, to undertake the evaluation we needed to have data relating to the number of patients eligible for treatment via the protocol before and after it was implemented. This data is needed to describe patient numbers at each of the key decisions within the protocol. We anticipated that routine electronic data would provide most of the data, with primary data collection being used to fill in the gaps. However, electronic data systems were found not to be capable of describing the majority of treatment decisions within the protocols that were candidates for study in the case study hospitals. These systems could describe admissions, transfers and operations easily, but the finer details relating to tests, medications and examinations were rarely recorded electronically. This left us requiring a much greater of amount of primary data collection than anticipated. This was compounded by the fact that most of the case study hospitals that we were able to recruit had already implemented their protocols, which meant that we were unable to collect our own data in the period before the protocol was implemented. At the case study site where a protocol was being developed, the process was delayed for over six months, and the implementation period was expected to take at least twelve months. Consequently, at this site we were unable to collect the necessary data after implementation.

The second problem that was uncovered whilst the literature review was underway was that the protocols that had been evaluated tended to be simple, single decision or referral, protocols. However, the protocols and guidelines within the case study sites

were much more complex, thereby requiring much more complex decision trees and much more data. Furthermore, it was felt that more complex protocols are unlikely to generate generalisable findings as different sites will have completely different sets of parameters within the models. Robinson and colleagues, for example, undertook an evaluation of the effect of an algorithm relating to the use of thrombolysis for suspected acute myocardial infarction (Robinson *et al*., 1998b) in several hospitals. Even for this very simple protocol, they found dramatic differences between the hospitals, such that the cost per extra case treated ranges from £81 to £1290.

In response to these problems, and following consultation with our Expert Panel and NCCSDO we decided to abandon our attempt to evaluate the cost-effectiveness of a protocol in each of the case study sites and focus our efforts on deriving detailed costs relating to the development and implementation of protocols at the sites. However, it was recognised that whilst it was unlikely that our original study would have been able to produce generalisable results, the results of an evaluation would still clearly be of value to the host organisation. Consequently, we set out below the important methodological information we have built-up during the literature search and our attempts to develop cost-effectiveness analyses in the case study sites.

7.2 Methods used in the economic evaluation of standardised care

Whilst we have shown that the vast majority of evaluations have not included all relevant costs relating to the protocols under investigation, their methods may still be of value as the missing costs can easily be incorporated into the analysis. Some of the studies also make important observations relating to the difficulties faced when evaluating attempts to standardise care, for example Robinson et al (1998). Also of note are several studies that have developed frameworks for evaluating behavioural change programmes (Gandjour, Lauterbach, Gandjour, & Lauterbach, 2003; Gandjour, Lauterbach, Gandjour, & Lauterbach, 2005; Mason *et al*., 2001), as these are relevant to the issue of standardised care.

7.2.1 Inadequate approaches

There are several examples of poor reporting of methods, and poor methods among the studies identified in the review of studies in the NHS Economic Evaluation Database (EED). Many studies present results without any hypothesis testing, so we are unable to determine whether the reported savings are statistically significant. Only in very limited situations could this be considered legitimate, for example, in the study by Robinson and colleagues, their study aimed to examine the cost of developing/implementing the audit and explicitly ruled out the costs of treatment consequences (Robinson *et al*., 1998b). Adopting this narrow perspective, removes the need to measure changes in direct patient care and therefore excludes variability in costs between patients.

7.2.2 Statistical approach

Within the remaining literature identified in the review, the majority of studies undertake a statistical analysis of mean costs before and after the introduction of the standardised care package. For example, Al-Eidan (2000) compares mean costs for the two patient groups and shows that the difference is unlikely to be due to chance (p<0.001).

7.2.3 Modelling approaches

An alternative approach is to structure the evaluation in the form of a model. Robinson and colleagues developed a model for evaluating the effects of a simple algorithm to identify patients that were eligible for thrombolysis (Robinson, Thompson, & Black, 1998a). The evaluation is thereby undertaken via a set of parameters, which are derived from an audit of the protocol, the literature or assumptions.

Mason and colleagues (2001) develop a more sophisticated model to look at prescribing. They highlight the fact that a behavioural change programme to implement cost-effective treatments, may not be cost-effective if the costs of development/implementation are high, patient numbers are small and/or the duration of the behaviour change is short. Their approach uses information on all of these factors and is illustrated by estimating the cost-effectiveness of two sets of guidelines. Whilst for one medication the results change little, for another, the estimated cost savings relating to the intervention are removed when implementation is factored in.

The work by Mason and colleagues has been developed further into a more complex mathematical approach (Gandjour *et a*l., 2003; Gandjour *et al.*, 2005), however, it is felt that these developments make it less useful for operational decision making.

Another modelling approach was adopted by Lotan and Roehrborn (2002) that transformed the protocol into a decision analytic model. This approach is more complex than that mentioned previously as it incorporates an evaluation of the cost-effectiveness of the consequences of treatment. The previous examples all 'bolted-on' pre-existing estimates of cost-effectiveness to their estimates of implementation costs, to come up with an overall figure. By mapping out all the consequences of treatment, the evaluation of Lotan becomes quite complex, requires expertise in modelling.

7.3 Discussion

The best developed approach for examining the cost-effectiveness of standardised care is that described by Mason and colleagues (Mason *et al.*, 2001). It clearly shows how development/implementation and duration of behavioural change all drive a wedge between 'treatment' cost-effectiveness and 'policy' cost-effectiveness. Their approach, however, was implemented in situations where the cost-effectiveness of the new treatment was already known. This was also the case in the modelling approaches used by Robinson and Gandjour (Gandjour *et al.*, 2005; Robinson *et al.*, 1998a).

When treatment cost-effectiveness is not already known, then more complex modelling is required to estimate this was part of the protocol evaluation. This approach suffers from several problems. Firstly, the effect of the protocol is typically estimated as the difference

between the pre- and post-protocol outcomes. However, this fails to guard against other factors that may change over the same period of time, in particular, other factors that influence clinical behaviour (Robinson *et al.*, 1998b). Secondly, many protocols aim to improve safety, and therefore, focus on quite rare events. Identifying changes in the number of these rare events is unlikely in small scale evaluations (Robinson *et al.*, 1998b). Finally, many forms of standardised care, especially guidelines and patient pathways, cover the whole disease pathway from diagnosis through to death. In these circumstances, an evaluation of the entire pathway becomes incredibly complex.

7.4 Recommendations

It is clear that the costs of development and implementation must be included in any evaluation of standardised care; inclusion of these costs can have a profound effect on the results and policy conclusions (Hoeijenbos *et al.*, 2005; Mason *et al.*, 2001). However, the evaluative framework that is best suited to the task needs to be carefully considered. The first issue that must be understood is the purpose of the protocol. Where the protocol is being developed for reasons other than improvements in treatment effects, a formal cost-effectiveness analysis is not appropriate as cost-effectiveness ratios can not be easily generated.

Also prior to any evaluation, the complexity of the protocol needs to be assessed; entire patient pathways covering dozens of treatment choices can not be reliably assessed in a single evaluation. Complex protocols may need to be broken up into smaller questions relating to the most important treatment decisions. Two important consequences of this must be understood. Firstly, not all aspects of the protocol may be formally evaluated. Secondly, an overall estimate of cost-effectiveness will not be produced.

Dismantling a protocol in this way produces another important set-back; the costs of development and implementation will relate to the full guideline and therefore should not be wholly allocated to each individual evaluation. In these circumstances, judgement needs to be used to assess how much of the development/implementation 'overhead' should be attributed to each individual evaluation.

The next key issue is whether evidence of cost-effectiveness is already available. Where good evidence is available, the modelling approach of Mason gives a clear and simple structure to the overall evaluation of the protocol development and implementation.

Where evidence is not available then the evaluation of treatment consequences needs to be undertaken simultaneously with the implementation of the protocol. When this is undertaken, care must be taken to control for other factors that may influence outcomes, and that differences are tested for statistically. One framework for such an evaluation that may be useful is the decision tree format, which was used by Lotan and colleagues (Lotan *et al.*, 2002). This allows the protocol to be easily visualised as part of the evaluation, and provides a framework that allows 'what-if' analyses to be quickly undertaken, which can help identify the effect of further changes on cost-effectiveness, e.g. 'what-if we were able to increase the number of patients receiving a particular test'. However, such an approach requires expertise in modelling and with more complex

questions, the model can quickly grow into something that becomes difficult to use at an operational level.

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